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CIS

RURAL DEVELOPMENT, AGRICULTURE, AND RELATED AGENCIES APPROPRIATIONS FOR 1991

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

SUBCOMMITTEE ON RURAL DEVELOPMENT, AGRICULTURE, AND RELATED AGENCIES

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RURAL DEVELOPMENT, AGRICULTURE AND RELATED AGENCIES APPROPRIATIONS FOR 1991

WEDNESDAY, MARCH 21, 1990.

OFFICE OF PUBLIC AFFAIRS

WITNESSES

PAUL E. KINDINGER, DIRECTOR, OFFICE OF PUBLIC AFFAIRS
STEPHEN B. DEWHURST, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

Mr. **WATKINS**. Our next witness is Mr. Kindinger of the Office of Public Affairs, and Mr. Akaka from Hawaii will Chair.

Mr. **AKAKA** [assuming chair]. Thank you very much. I'm glad you're here at the table, Mr. Kindinger, and we look forward to your testimony.

Dr. **KINDINGER**. Thank you, Mr. Akaka and Mr. Skeen.

We do appreciate the opportunity to be here. You have my written testimony. I'm going to paraphrase from that and summarize in the interest of time so that we can get directly to the questions.

This is my first opportunity to be before the committee, and I want to say that I'm honored to do so. I look forward to working with you.

REORGANIZATION

The Office of Public Affairs that we're talking about today was established by the Secretary of Agriculture on October 1st of last year.

The reorganization was a separation between the office that's now the Office of the Assistant Secretary for Congressional Relations and the Office of Public Affairs.

It used to be called the Office of Governmental and Public Affairs, so they're now two separate entities. Within the Office of Public Affairs, our redefined activities are responsibility and Intergovernmental Affairs, which include liaisons with State and local governments and Indian tribal councils.

We have the Office of Publishing and Visual Communication, which is primarily our working capital fund, doing video production, teleconferencing, design, photography, publishing and printing.

Then we have our Office of Press and Media Relations, which is our radio and television media, as well as our news division; our Office of Public Liaison, which works with many of the food and agriculture groups and the trade and consumer associations. Our Office of Programs and Planning is responsible for strategic planning, as well as evaluations. They do some of our Freedom of Information Act requests and things of that nature.

OFFICE OF PUBLIC AFFAIRS ACTIVITIES

For 1991, we plan to continue many of our traditional activities such as the yearbook, meeting with the constituent groups and interactions with Governments and Native American programs, and we also want to expand our outreach to minority populations.

We're also working with several cross cutting issues. I'm sure you've all had inquiries and interest in areas such as food safety, water quality, animal welfare, rural development and biotechnology.

Many of these cross cutting issues are ones that the public is demanding to know more and more about, and we feel that we have a responsibility to do that.

In addition, during 1991, we have items like the Farm Bill and the General Agreement on Tariffs and Trade negotiations, and even though they will have been passed, hopefully, by Congress at that time, there's still a huge job of explaining how those will work in the countryside and the impact on farmers' lives and the food and agriculture industry.

Besides those challenges in 1991, we're improving on the management within public affairs and the overall operation, and our goal is to foster more innovative, efficient ways to meet the public affairs needs of USDA.

FY 1991 BUDGET REQUEST

Specifically, our request is for $8.882 million, which represents an increase of $389,000 over the fiscal year 1990 appropriation, and that's primarily to cover inflation for many of the things that we do and to cover a portion of the mandated pay raises that were just recently enacted.

Mr. Chairman, I'll stop here and answer any questions you may have.

[Clerk's note.—Mr. Kindinger's biographical sketch appears on page 18. Mr. Kindinger's statement appears on pages 19 through 21. The explanatory notes appear on pages 22 through 34.]

Mr. Akaka. Thank you very much, Dr. Kindinger. We welcome you, especially now that this is your first experience here before the committee.

Dr. Kindinger. Thank you.

BROWN TREE SNAKE

Mr. Akaka. You described your responsibilities very well. One of them happens to relate to a situation that's becoming serious in the Pacific and in Hawaii, and I notice in your budget notes you indicate that the Office of Intergovernmental Affairs continues to serve as USDA's representative in discussions with the Commonwealth of Guam that the Interior Department and Defense Department aimed at dealing with the economic devastation caused by the brown tree snake.

Dr. Kindinger. Yes.

Mr. **Akaka**. In Hawaii, we are seriously concerned with the possibility of that snake appearing in Hawaii, and I was informed that one of them was found on the island of Kauai.

So it is very serious for us. Last fiscal year I included $2 million in the fiscal year 1990 Interior appropriations bill for research into preventive measures to alleviate the economic losses on Guam and prevent the accidental introduction of the brown tree snake into Hawaii and other Pacific islands, or to the mainland.

I can see where one of them or more than one has slipped through already. I also understand that you are working with other agencies such as Interior and Defense on an agreement before the Animal Damage Control Unit of APHIS can take over from the Office of Public Affairs.

My question is what is the current status of your discussions with the Commonwealth and with the Interior and Defense Departments, and has an interagency agreement been signed, and if not, what is delaying the conclusion of an agreement?

Dr. **Kindinger**. Mr. Akaka, I would have to plead that I do not have those details, but our Director of Intergovernmental Affairs who has been actively involved in that does have them, and we will supply them to you.

[The information follows:]

USDA's Animal Damage Control (ADC) prepared a proposal for operational control of brown tree snakes in July 1989 which was presented to the Pacific Basin Development Council (PBDC). USDA was told later that the PBDC had declined the ADC proposal in favor of one from the Fish and Wildlife Service (FWS), which included only research.

On December 6, 1989, USDA officials met with representatives from the U.S. Department of Interior on the brown tree snakes issue. Deputy Assistant Secretary for Territorial and International Affairs, Bill Houston, indicated a strong desire for ADC to participate in a control program. He asked that USDA work with representatives of the FWS to draft an agreement that would include both research and operational control. It has been very clear from the beginning that the FWS researchers wanted to use the entire $1 million appropriated for work on the brown tree snakes for research. USDA's position has been that any control work or any involvement by the ADC program would have to be done through reimbursement by the Department of the Interior or the Government of Guam.

In January 1990, it was finally agreed that ADC would play no role in the current research and control effort. However, they would like the Denver Wildlife Research Center to provide advice and recommendations regarding development of chemical controls.

Based on these latest discussions, it appears that the roles of the various agencies interested in controlling the brown tree snakes have finally been defined. APHIS' role will be limited to assistance from DWRC in development of any chemical controls that may be used. There will be no further participation by ADC in the brown tree snakes project.

Mr. **Akaka**. Mr. Skeen?

Mr. **Skeen**. Thank you, Mr. Chairman.

Welcome, Dr. Kindinger.

Dr. **Kindinger**. Thank you.

PUBLIC AFFAIRS INVOLVEMENT

Mr. **Skeen**. I appreciate very much the fact that a man of your background has taken this position, and I don't think that there's any more important office for agriculture or any of the other agencies that are so much involved in public affairs today as the Public Affairs Office.

In the past, it's been far too evident that when a public issue arises, it's been very difficult to find a voice in Government that would either respond with some intelligence, or know with a certain amount of knowledge that they should be custodians of that particular issue.

ANIMAL WELFARE

I have a question from Congressman Weber and myself on an issue we share an interest in. You mentioned the cross cutting issues, and one of them involves animal welfare. I'd like to know what your office has been doing in that particular area and if you have taken any stand on the issue.

Dr. **Kindinger**. I can try briefly to give you a thumbnail sketch of that.

Mr. **Skeen**. I would appreciate that.

Dr. **Kindinger**. We do have a great deal of concern. There are a number of people who are active in that area, and they seem to have a lot of money to deal with the approach. But in our case, we have a team of public affairs people we've put together to examine an information program beginning with school children, because we believe it's important to understand not only agriculture, but the importance of animals and the role they play, not only in agriculture, but in the medical community and a number of other ways that they're important to humans in every day life.

We're also looking at making sure that we communicate clearly about USDA's role that Congress has provided for us, mandated through legislation over the years, through the Animal Welfare Act and other activities such as that of making sure that the public understands what we currently do in that area. I'm not sure that we've done that in the past, so we need to do a better job of that.

In addition, we're looking at putting out a variety of factual information to the public to make sure, again, that they not only understand animal agriculture as well as we can explain it, but the importance of that and the impact on their everyday life.

So we're looking at a pretty broad spectrum approach, a positive approach, predominantly aimed at informing and educating people about animal agriculture and what USDA and other agencies throughout Government, quite frankly, are doing.

Mr. **Skeen**. I'm assuming, too, that also includes the responsibility that USDA has for providing certain standards and regulations.

Dr. **Kindinger**. That is correct.

Mr. **Skeen**. Please provide a copy of all material your office has produced on the animal welfare issue.

Dr. **Kindinger**. The animal welfare issue team was only recently formed. It is still in the process of completing a committee plan. We expect materials to be forthcoming later in FY 1990.

Mr. **Skeen**. Please provide a copy of all requests your office has received during the past 14 months for information on the animal welfare issue and include the informaton that your office provided in responding to those requests.

Dr. KINDINGER. Information about the animal welfare issue has been requested by GAO as part of its request for information concerning the public affairs issue teams. Relative to that request, the Office of Public Affairs released a copy of the issue team member list.

A request was received by OPA under the Freedom of Information Act from the National Association for Biomedical Research for documents pertaining to the animal welfare issues team. All information relative to the request was withheld under the deliberative process privilege.

Mr. SKEEN. I appreciate that response very much. Thank you.

Thank you, Mr. Chairman.

Mr. AKAKA. Thank you, Mr. Skeen.

RESPONSIBILITY IN THE PROGRAM OF OPA

I don't know whether you had anything to do with it, but I understand you moved into USDA on July 30, 1989. You also stated here that October 1st was when this office was established, which tells me that you had some responsibility in the formation of OPA.

I also understand that the program you have is considered an ambitious one, and you've stated it, too, in your testimony, and that you will have also the responsibility for explaining the Farm Bill and the Uruguay Round, which will be of interest to me and to my colleagues.

Also, as you said here, you are expanding a minority outreach and developing Public Affairs issue teams to respond to public inquiries, and that's going to be a big issue when we talk about food safety and water quality and animal welfare, to name but a few.

Your budget seeks to raise $389,000 to cover operating costs, inflation and pay raises.

Dr. KINDINGER. That's correct.

Mr. AKAKA. Do you believe that your current staff level is sufficient to respond to your increased ambitious program that you have for OPA?

Dr. KINDINGER. Well, that's an excellent question, Mr. Chairman, and I would respond by saying that we are doing a number of things administratively and organizationally to try and make sure that we're operating as efficiently as we possibly can. I have found a number of areas where we've been able to make improvements, and that allows us the ability to move some staff and dollars around.

In addition to that, as you recognize, I would comment that the amount of money in the budget only partially covers some of the pay increases, so that will have an impact on our ability to do programs, obviously.

I don't know what the exact percentage is, but it's——

Mr. DEWHURST. It covers half.

Dr. KINDINGER. It covers roughly 50 percent of the pay increases, so we will have to absorb the other half. Quite frankly, there are a number of other issues besides the ones that I've mentioned on which we're going to have to do public affairs campaigns. We're concerned, but I'll do everything in my power to make it work.

Mr. AKAKA. Well, thank you for that. I was just trying to reach in there and see how you are really going to carry this out in a timely and thorough manner. I'm interested in your program.

Dr. KINDINGER. Well, I do appreciate your concern.

Mr. AKAKA. Certainly, we look toward informing the public as much as we can, and that's an important mission that you have.

So I'm glad to hear that you have some of these problems, and maybe we can help.

Dr. KINDINGER. Thank you very much.

Mr. AKAKA. Mr. Whitten?

COMMODITY CREDIT CORPORATION

Mr. WHITTEN. The 1988 Yearbook is titled *Marketing U.S. Agriculture*. The index lists six pages where there is reference to the Commodity Credit Corporation. Yet, in those six pages not once does it explain that CCC can be used to sell U.S. agriculture products on the world market for what it will bring. How can you talk about marketing agriculture and not explain the Commodity Credit Corporation?

Dr. KINDINGER. The lack of an explanation of the Commodity Credit Corporation's role in acquiring and selling U.S. products at home and abroad was an oversight in the 1988 Yearbook of Agriculture. The yearbook, *Marketing U.S. Agriculture*, aimed primarily to help farmers and others improve their marketing efforts. A chapter explaining the CCC could have been included in Part I, which gave an overview of how the U.S. marketing system for food and fiber works. However, the export programs available under the CCC were fully detailed in Part VII, which covered Government and other resources for farmers and firms.

YEARBOOK OF AGRICULTURE

Mr. WHITTEN. The 1989 Yearbook of Agriculture is titled "Farm Management: How to Achieve Your Farm Business Goals". It includes chapters dealing with such issues as how to enter farming and where to get credit. How will this book help the 300,000 farmers that have already gone out of business?

Dr. KINDINGER. We agree that it is most unfortunate that many farmers have gone out of business. Your point is well taken. It is unlikely that the book will be of assistance to those who have already been displaced. However, the 1989 Yearbook was dedicated to helping American farmers survive and succeed in their businesses, as Secretary Yeutter said in his Foreword to the book. The USDA staff who worked on the book, as well as the farm management and other experts who wrote chapters, aimed to help farmers who read the book enhance their business management skills and thus be better able to achieve their goals. Perhaps the 1989 Yearbook will help save some of those who might otherwise have gone out of business.

Mr. WHITTEN. Please update the table that appears on page 17 of last year's hearing record showing the number of Yearbooks sold by the Government Printing Office to include 1989.

Dr. KINDINGER. I will be happy to update the table.

[The information follows:]

Number of Yearbooks of Agriculture Sold by the Government Printing Office (1984-1989)

1984	4,040
1985	8,244
1986	3,270
1987	4,418
1988	4,343
1989	4,564

Mr. **Whitten**. What is the status, title and working outline for the 1990 Yearbook?

Dr. **Kindinger**. The 1990 Yearbook of Agriculture will be about people in American agriculture. Chapters have been assigned to cover over 70 authors, and manuscripts are arriving now. The book will tell the stories of Americans involved in all aspects of agriculture—including a diverse group in production agriculture. It will help farm and nonfarm audiences appreciate the breadth and significance of agriculture in our economy and society, and will encourage young people to consider agriculture as a career. The Yearbook will also celebrate the Centennial of the 1890 Institutions, the traditionally Black Land Grant schools, with several case studies highlighting activities of people associated with these Institutions. I will provide a very brief working outline of the 1990 Yearbook.

[The information follows:]

A. Introduction: Who Works in American Agriculture Today?
B. Who Are America's Farmers? (approximately 10 chapters, mostly case studies)
C. The Business of Agriculture (approximately 20 case studies)
D. The Science of Agriculture (approximately 10 chapters, mostly case studies)
E. Education: The Future of Agriculture (approximately 12 chapters, mostly case studies)
F. Public Employees Serving Agriculture (approximately 10 chapters)
G. Retail customers for U.S. Agricultural Products (photo features)

Mr. **Whitten**. How are the subjects of the Yearbook decided each year?

Dr. **Kindinger**. Each year, the Secretary of Agriculture chooses a topic for the Yearbook of Agriculture after reviewing possible topic ideas from the Office of Public Affairs, various Department officials, and other people who make suggestions.

BUDGET INCREASES

Mr. **Whitten**. Please provide an object class breakdown of the $82,000 requested increase for operating costs for Public Affairs and the $3,000 requested for Intergovernmental Affairs.

Dr. **Kindinger**. I will be glad to, Mr. Chairman.

[The information follows:]

OFFICE OF PUBLIC AFFAIRS REQUESTED INCREASE FOR OPERATING COSTS

(FY 1991)

Object Class		Public Affairs	Intergovernmental Affairs	Total
2100	Travel and Transportation of Persons	6,000	1,000	7,000
2200	Transportation of Things	1,000		1,000
2300	Rent, Communications, and Utilities	48,000	1,000	49,000
2400	Printing and Reproduction	57,000		57,000

OFFICE OF PUBLIC AFFAIRS REQUESTED INCREASE FOR OPERATING COSTS—Continued

(FY 1991)

Object Class	Public Affairs	Intergovernmental Affairs	Total
2600 Supplies and Materials	3,000	1,000	4,000
Total Operating Increase	115,000	3,000	118,000
Planned Operating Reduction (Object Class 2500)	−33,000		
Net Operating Increase	82,000	3,000	85,000

TRANSFERS FROM OTHER AGENCIES

Mr. WHITTEN. Your explanatory notes indicate a transfer from other USDA appropriations accounts of $4,379,000 to the Office of Public Affairs. For the record please provide a table showing the amount of transfer from each agency.

Dr. KINDINGER. The total of $4,379,000 represents estimated reimbursements of $3,729,000 from other USDA agencies for services provided by the Office of Public Affairs' Working Capital Fund entities. Also included in the total are reimbursements of $585,000 for agency photography services, $50,000 for administrative support to the Working Capital Fund, and $15,000 for the Ag Journalism Conference.

[The information follows:]

Reimbursements to OPA from other USDA appropriations

(In thousands of dollars)

Agricultural Cooperative Service	46
Agricultural Marketing Service	100
Agricultural Research Service	425
Agricultural Stabilization and Conservation Service	51
Animal and Plant Health Inspection Service	364
Cooperative State Research Service	103
Departmental Administration	151
Economics Management Staff	92
Economics Research Service	44
Extension Service	211
Farmers Home Administration	278
Federal Crop Insurance Corporation	2
Federal Grain Inspection Service	24
Food and Nutrition Service	244
Food Safety Inspection Service	247
Foreign Agricultural Service	169
Forest Service	844
Graduate School	3
Human Nutrition Information Service	37
National Agricultural Library	80
National Agricultural Statistics Service	10
Office of Budget and Program Analysis	5
Office of Public Affairs	342
Office of the Inspector General	18
Office of International Cooperation and Development	8
Office of the General Counsel	3
Office of the Secretary	44
Office of Transportation	9
Packers and Stockyards Administration	3
Rural Electrification Administration	20

Soil Conservation Service	338
World Agricultural Outlook Board	6
Non USDA	58
Total	4,379

MEDIA SERVICES

Mr. WHITTEN. USDA provides a variety of radio and television services to broadcast media. Were there any new services provided in fiscal year 1989? If so, please list them.

Dr. KINDINGER. There were no new services offered to broadcasters in FY 1989. However, there was increased emphasis on TV news actualities and features. In calendar year 1989, there were 233 more radio items produced, 201 more television actualities and 112 more features produced than in 1988.

Mr. WHITTEN. Were any previous services deleted? If so, what was the reason for deleting them?

Dr. KINDINGER. The one-half hour weekly TV program "A Better Way" was canceled. Following notification to stations, production of the program ended November 16, 1988. Final telecast by satellite was performed November 28, 1988.

A Nielsen Media Research Report survey on syndicated programs taken in the first quarter of calendar year 1988 revealed that "A Better Way" was being broadcast on only 22 commercial television stations of the over 900 such stations existing. The Report showed that at the majority of stations, 18 of the 22, the household share and number of viewers of "A Better Way" was too small to measure.

The program was designed to serve as USDA's vehicle to reach the general public with agricultural information. The Nielsen numbers indicated that the program was not meeting its purpose of informing the American public. The program was the most expensive single item in the Division's production budget. Re-allocation of remaining funds to other TV projects offered the opportunity to improve the TV service within the existing budget. Re-allocation of the one producer from the program to remaining programs and reallocation of funds was accomplished in late December 1988.

The weekly series of five 5-minute TV Programs "Down to Earth" was canceled. Following notification to stations, production of the series ended February 20, 1989. Final telecast by satellite was performed February 27, 1989.

Conversation with TV farm broadcasters at regional and national meetings of the National Association of Farm Broadcasters, and conversation by telephone with station TV producers using the program strongly indicated that it was becoming less useful to farm broadcasters. The majority of broadcasters contacted in the telephone conversation stated that they did not use the program. The majority stated that the programs were too long to fit into their schedule; that they preferred material that was shot outside a studio; and that they wanted a variety of material such as B-roll which they could use to edit their own items. The program format was not flexible enough to accommodate these needs.

The majority of TV broadcasters contacted were enthusiastic about the TV News Service. The material is shorter in length and produced outside the studio. TV News Service offers enough flexibility to provide B-roll, raw footage, features, a wider variety of material, and in a form that is more usable to broadcasters.

Cancellation of "Down to Earth" resulted in improved use of budget and personnel and allowed OPA to expand the Department's TV message used by broadcasters.

Mr. WHITTEN. According to the explanatory notes, OPA provides photographic research services and distributes photographs to the news media free of charge, but charges the public a nominal fee to cover the cost of reproduction. How many such services were provided last year?

Dr. KINDINGER. During fiscal year 1989, the Office of Public Affairs' Photography Division responded to 1,282 requests for visual materials resulting in the distribution of 2,913 black and white prints and 1,489 color slides.

Mr. WHITTEN. What was the cost to OPA?

Dr. KINDINGER. The cost of obtaining reproductions from local lab facilities, to fill requests from the news media was $693 for prints and slides.

Mr. WHITTEN. How much in fees was collected?

Dr. KINDINGER. Income from the sale of these prints and slides amounted to $8,627.

Mr. WHITTEN. Why aren't the news media also charged a nominal fee to cover the cost of reproduction?

Dr. KINDINGER. We do not charge the media for prints and slides because the media are a conduit through which we are able to reach the public. This conduit assists USDA to disseminate visual information relating to current events affecting agriculture and the programs administered by USDA.

Photographs are an integral part of USDA's public information and education effort. We encourage the use of USDA photographs through national and regional distribution of illustrated news and photo features.

Mr. WHITTEN. Please update the Committee on the status of the project OPA and the National Agricultural Library are collaborating on to convert the Photo Library to optical disc storage.

Dr. KINDINGER. The Office of Public Affair's Photography Division completed the first 12-inch laser disc with a computerized database in December 1989. The disc, including the "picture record" data, is available for $445 from the National Technical Information Service in Springfield, Virginia.

The disc contains approximately 15,000 photographs illustrating broad areas of agriculture, food and nutrition, insects, plant and livestock diseases, forestry, and resource conservation. It also contains two short videos and four public service announcements produced by USDA plus other illustrations from rare books and paintings from the National Agricultural Library special collections. We are currently discussing the future of this project with the National Agricultural Library.

Mr. WHITTEN. Will farmers be able to utilize this form of information?

Dr. KINDINGER. Yes, the optical disc serves as a source for farmers and the general public to find information on the photographs illustrating American agriculture and USDA activities and programs. The disc will be available to farmers and others through land-grant universities, local libraries, and other government agencies in and outside Washington, DC. We feel the new technology will broaden and expedite service to the public, the media, and USDA agencies through the remote work stations and through the search capability of the database.

Mr. WHITTEN. On page 3g-3 of the explanatory notes, you state that television items transmitted via satellite for the January-September period increased from 341 in 1988 to 626 in 1989 due partly to a shift of personnel. How many staff were involved and where did this shift take place within OPA?

Dr. KINDINGER. Two TV production specialists were shifted to the TV News Service. One became available following cancellation of "A Better Way" and one became available following cancellation of "Down To Earth." Both positions were already members of the TV staff.

Mr. WHITTEN. When and where will the 12-minute special project "Agriculture—The Most Crucial Industry" be aired?

Dr. KINDINGER. The program was designed to be shown to live audiences rather than for broadcast on a TV station. The main factor that mitigates against airtime is its length, 14 minutes 30 seconds, although stations are welcome to broadcast it. A news release has been issued to the media regarding the program. The program is available to the public through the National Audiovisual Center and through Video Transfer. The Foreign Agricultural Service has obtained 80 copies for distribution to their attaches around the world. It has been shown to senior policy makers at the Department, and to agency public affairs specialists. It was transmitted via satellite to broadcast stations March 31 and April 2, 1990.

Mr. WHITTEN. Are any more special projects for television in the works? If so, what are they?

Dr. KINDINGER. There are many issues that deserve the expanded treatment of special TV programs, among them include items such as General Agreement on Trade and Tariff proposals and international trade, water quality, erosion control, rural development, low input agriculture, food safety, chemical use, forestry, nutrition, food stamp programs, animal welfare and others. We are attempting to meet these needs within current budget constraints.

DESKTOP PUBLISHING

Mr. WHITTEN. OPA established a desktop publishing committee in fiscal year 1989. Please describe in detail the concept of desktop publishing and what this committee hopes to accomplish.

Dr. KINDINGER. Desktop publishing arrived in 1986 with the release of Aldus software for the MacIntosh and the new personal laser print technology. The term "desktop publishing" refers to the act of preparing camera-ready art or copy for a document using a personal computer and laser printer. "Electronic publishing" encompasses desktop publishing but the software also includes professional typesetting capability. The Electronic Publishing Committee was initiated by the Design Division in September 1986 to address the potential proliferation of desktop publishing equipment in USDA.

At the time of its formation, the committee met monthly to deal with the new technology, its impact on USDA and the flow of information in the Department. Guest speakers were invited to meetings, and "field trips" were taken to evaluate other systems before one standard would be chosen for USDA agencies.

However, it became clear that no one system would effectively address the needs of all users in the Department. It was therefore established that the committee would play the role of an advisory board, sharing the experience of users with various software and hardware. The meetings became quarterly, and eventually semiannual.

Now that electronic publishing is more common in USDA, and most agencies have selected their desktop publishing systems, the present role of the committee is one of a network or users' group. It meets to review recent developments, discuss concerns, and establish standards for the Department as necessary.

REORGANIZATION

Mr. WHITTEN. The responsibilities of OPA are divided between five offices. For the record, provide a description of each office including duties, number of staff, budget, etc.

Dr. KINDINGER. The Office of Public Affairs' operating programs are performed within five offices. I will provide these for the record, but these budgets do not include the Office of the Director.

[The information follows:]

Office of Intergovernmental Affairs: USDA liaison for State and local government officials including Indian Tribal Councils, and the White House Office of Intergovernmental Relations.

Staff: 6

Total budget: $421,000

Office of Public Liaison: Develops and maintains liaison with the food and agriculture industry, and trade and consumer associations or other specialized interests seeking interaction with USDA.

Staff: 4

Salaries and benefits budget: $252,806

Office of Programs and Planning: Responsible for strategic planning of new public affairs programs, coordination of issues teams and reviewing existing public affairs programs.

Staff: 16

Salaries and benefits budget: $932,708

Office of Press and Media Relations: Directs information programs targeted to radio, television and print media.

Staff: 25

Salaries and benefits budget: $1,313,352

Office of Publishing and Visual Communication: Plans, produces and distributes all print and video information materials. OPVC provides centralized services financed through the Working Capital Fund for video production, teleconferencing, design, exhibits, photography, printing and publishing.

Staff: 63

Salaries and benefits budget: $2,525,771

Mr. WHITTEN. In your testimony you state that you will expand your outreach to minority populations through radio and printed material. Please describe in further detail how you will achieve this goal.

Dr. KINDINGER. Through a variety of programs we feel we have made a concerted effort since October 1989 to increase our awareness of minority concerns and increase our information outreach to minority audiences. The 1990 Yearbook of Agriculture will be a celebration of the Centennial of the 1890 Institutions, the traditionally Black Land Grant schools. The Yearbook editor has worked closely with Samuel Donald, Dean of Agriculture at Alcorn State University in Lorman, Mississippi, who represents the 1890 Institutions. Together, they have developed several chapters for the 1990 Yearbook that highlight activities of people associated with these institutions. The 1990 Yearbook will also include other chapters that encourage women and minorities to consider agricultural industries and USDA as potential careers.

Our News Division has started AGfocus, a compilation of story ideas on agricultural topics that we send to media identified as having a high miniority readership. The first has just gone out to black publications but we intend to expand AGfocus to other minority groups including women, Asian Americans, and Hispanics. AGfocus will be issued any time there is information about USDA programs which we think will be of interest to specific audiences. Topics may include nutrition, career opportunities, scholarships or feature stories about professionals at USDA.

We have indentified and complied a mailing list of 325 newspapers and periodicals with high percentages of minority readership, and are in the process of adding radio and television stations with predominately minority audiences to this list. These media outlets will recieve AGfocus as well as regular news releases about food and nutrition programs, nutrition, food safety, careers, limited resource farming, and consumer issues.

The News Division also prepares and mails Spanish language broadcast news tapes containing information about USDA programs and consumer issues weekly to 225 radio stations which broadcast in Spanish. We have recently updated a mailing list of 124 hispanic publications and television stations. These receive regular news releases on topics we feel will be of interest. The Deputy Director of OPA is a member of the Hispanic Employment Program and reports back to OPA Directors the concerns of Hispanic USDA employees and possibilities for employment and training.

We also intend to increase our knowledge of minority media needs by sending representatives to Hispanic and Black media association meetings this year.

Currently, OPA is working on a report to the Congressional Research Service, CRS, of the Library of Congress to give specific details of USDA programs of assistance to Americans Indians. CRS will publish the report for use by Indian Tribes' officials and others who are interested. OPA is also working on a similar report for OMB.

The agenda for a joint meeting on April 4, 1990, of the Intertribal Agriculture Council, IAC, and the American Indian and Alaska Native Agriculture Network, AIANAN, is also being developed in OPA. The IAC consists of leaders of sources of Indian Tribes that are interested in fostering better agriculture among Native Americans on and off the reservations. The AIANAN, initiated by an OPA staffer, serves as a network for individuals in Federal agencies and private organizations also interested in the same goals as the IAC.

An OPA staff member serves as Program Chairman of the USDA Federal Women's Program. The mission of the Federal Women's

Program is to educate and train women in USDA for upper management positions.

PUBLIC AFFAIRS ISSUE TEAM

Mr. **Whitten**. Please list each Public Affairs Issue Team that has been formed or is planned and include who are members of these teams and what each will do.

Dr. **Kindinger**. The purpose of the teams is to develop and implement communications plans for USDA's activities in support of a number of specific initiatives. The initiatives include such areas as food safety, water quality, Africanized bees, animal welfare, rural development, research and biotechnology, the 1990 Farm Bill, and General Agreement of Tariffs and Trade negotiations.

Although not tasked with designing policy, the teams will be guided by USDA's Policy Coordinating Council, composed of members of the Secretary's senior staff.

Composed mostly of public affairs specialists from various program agencies and the Office of Public Affairs, the role of the issue teams is to develop creative, innovative, and cost-effective strategies for communicating the policy to farmers and the public. These strategies will culminate in the team's development and implementation of a bonafide plan with specific communication activities. Members of the teams generally represent those agencies and offices having some degree of direct interest in the issue. As the plans are implemented, members of the teams and the agenices they represent will be involved accordingly.

Teams will be activated when a potential issue is recognized as being of major interest to USDA, farmers and the food and agricultural industry.

MANAGEMENT IMPROVEMENTS

Mr. **Whitten**. What management improvements are you making in the overall operation of OPA?

Dr. **Kindinger**. The division of the Office of Public Affairs into five offices has resulted in a clearer delineation of duties and responsibilities. Each office director has been tasked with streamlining management and increasing responsiveness to the public and within USDA. Each director now has to write a weekly activity report to help with our supervising the accountability of each office.

The budget, previously divided between the offices, has now been centralized. All requests for expenditures must be cleared by the Deputy Director or the Director of OPA. This process gives us the opportunity to review all requests for travel, equipment and programs.

In October 1989, the Director, Office of Public Affairs requested each office in OPA to complete a management challenge exercise which required a review of every operation in their area and recommendations of adjustments in operation. We meet periodically to review management procedures and assignment activities. This results in an ongoing process of management streamlining and improving internal communications.

With the purchase and installation of the Hewlett Packard HP3000 computer, we have begun the process of transferring our manually kept records into an electronic mode of vastly improved ability to manage distribution of Congressional allocations of publications. Soon, we expect to have a database containing information on all the Department's publications. Also, the database will contain the names and telephone numbers of subject matter and resource specialists within USDA and the agriculture community. This wealth of information will enable our staff to respond quickly and accurately to the thousands of requests we receive from the Congress, from press and media, academia, and the public, on matters pertaining to agriculture.

PRESS RELEASES

Mr. **Whitten**. Please update the table that appears on page 18 of last year's hearing record showing the number of press releases issued by OPA to include fiscal year 1989.

[The information follows.]

Number of News Releases Issued by the Office of Public Affairs

(Calendar Years 1985–1989)

1985	1,358
1986	1,300
1987	1,616
1988	1,720
1989	1,688

OTHER SERVICES

Mr. **Whitten**. Please provide a sub-object class breakdown for "Other Services" for fiscal years 1989, 1990 and 1991.

Dr. **Kindinger**. I will provide that information.

[The information follows:]

OFFICE OF PUBLIC AFFAIRS "OTHER SERVICES" BY SUB-OBJECT CLASS

Sub-Object Class	1989 (Actual)	1990 (Est)	1991 (Est)
2500 Other Services	24,000	18,000	18,000
2510 Contractual Services Performed by Other Federal Agencies	478,000	367,000	351,000
2520 Related Expenditures	37,000	29,000	27,000
2530 Repair, Alteration or Maintenance of Equipment, Furniture or Structures	97,000	74,000	71,000
2540 Contractual Services-Other	118,000	91,000	87,000
2559 Agreements-Other	11,000	8,000	8,000
2562 OIRM Computer Services Unit	19,000	15,000	14,000
2570 Miscellaneous Services	200,000	153,000	147,000
2580 Fees	6,000	5,000	4,000
Total	990,000	760,000	727,000

Mr. **Akaka**. Mrs. Smith?

DIVISION OF AGENCY

Mrs. **Smith**. On October 1, 1989, Secretary Yeutter ordered the establishment of the Office of Public Affairs. This office retained two of the three functions performed by the former Office of Governmental and Public Affairs—these responsibilities are public and intergovernmental affairs.

Would you please describe to the subcommittee whether the majority of the resources being requested by your office would be used for public affairs requests or for intergovernmental activities?

Dr. **Kindinger**. The majority of the resources our office requested will be used for public affairs. Requested resources for public affairs functions amount to $8,442,000, ninety-five percent of the total request, while requests for intergovernmental activities total $440,000, five percent of the request.

Mrs. **Smith**. Has the Office of Public Affairs been involved in many efforts to coordinate the activities of local, state, and Federal Government departments and agencies?

Dr. **Kindinger**. Through the Office of Public Affairs, the Office of Intergovernmental Affairs, OIA, serves as USDA's liaison with state and local governments. Further, the OIA serves as facilitator between the Secretary of Agriculture and the state Food and Agricultural Councils, which are composed of USDA State Agency Directors.

OIA monitors the activity of state and local governments and works with them to provide valuable and appropriate information on key agricultural and rural issues to USDA officials. In addition, OIA responds to inquiries and requests from these associations either directly or through the appropriate government agency. I will provide for the record a list of these government entities and associations.

[The information follows:]

1. State Department of Agriculture/National Association of State Departments of Agriculture (NASDA) and regional associations.
2. Governors' Offices/National Governors Association (NGA).
3. County Governments/National Association of Counties (NACo).
4. National Conference of State Legislatures (NCSL).
5. Council of State Governments (CSG).
6. American Legislative Exchange Council (ALEC).
7. U.S. Conference of Mayors.
8. National League of Cities (NLC).
9. National Association of Towns and Townships (NAT&T).

OIA recently arranged an extensive briefing on the administration's farm bill proposal for the National Association of State Departments of Agriculture. OIA is currently arranging for a similar briefing for the Food and Agriculture Committee of the National Council of State Legislatures.

The Office of Public Affairs works with other cabinet agencies as needed on cross-cutting issues such as safety, pesticide use, water quality, etc.

FY 1990 SEQUESTRATION

Mrs. **Smith**. In reviewing this office's budget, I note that in FY90 it received nearly $8.5 million. As we all recall, sequestration. . . . But, I notice that your office was not required to take a reduction like other agencies in the Department.

Would you briefly explain why this is true?

Dr. **Kindinger**. Since the Office of Public Affairs' appropriation of $8,882,000 was less than our post-sequester amount of $9,080,000, we were not required to take a reduction.

AG YEARBOOK

Mrs. **Smith**. In your testimony, you mention that your office would continue to be responsible for the traditional activities involving the publishing of the Yearbook for Agriculture.

I must say that this publication has been especially popular in my home state of Nebraska. Annually, I receive hundreds of personal requests for the yearbook. I also try to provide copies to the libraries in my district.

Would you briefly explain to the committee the demand and success of the Ag Yearbook in previous years? Is the Department committed to the continuation of this publication?

Dr. **Kindinger**. USDA is committed to continuing publication of the Yearbooks of Agriculture, as they are required by legislation under Title 44 of the U.S. Code.

Mr. **Akaka**. Mr. Weber?

PUBLIC AFFAIRS

Mr. **Weber**. It has been brought to my attention that the department has or is forming an animal welfare issues team. It is also my understanding that the public affairs department is involved in this matter. Could you tell me if this is true and, if so, what this is all about?

Dr. **Kindinger**. Yes, the public affairs department is involved. We have a team of public affairs people putting together an information program that will begin with school children. We believe it's important for them to understand agriculture, and the important role animals play, not only in agriculture, but in the medical community, and the number of other ways that animals are important to humans in everyday life.

We're also making sure that we communicate clearly about USDA's role mandated by Congress over the years, particularly in the Animal Welfare Act. We need to help the public understand what we currently do in this area.

In addition, we're looking at providing factual information to the general public, again ensuring that they understand animal agriculture and how it impacts on their everyday life and benefits America.

We're taking a pretty broad spectrum approach, a positive approach, predominantly aimed at informing and educating people about animal agriculture and what USDA and other agencies throughout Government are doing.

Mr. **Akaka**. Further questions?

Mr. **Skeen**. None.

Mr. **Akaka**. Thank you very much.

Dr. **Kindinger**. Thank you, and I look forward to working with you and hearing some of your ideas.

BIOGRAPHY:

PAUL E. KINDINGER
Director, Office of Public Affairs
U.S. Department of Agriculture

Dr. Paul E. Kindinger was appointed Director, Office of Public Affairs for the U.S. Department of Agriculture on July 30, 1989, by Secretary of Agriculture Clayton Yeutter.

In this post, Dr. Kindinger oversees the Department's media and public information activities, as well as, liaison with state governments and private corporations. He reports directly to the Secretary.

From November 1983 until his USDA appointment, Dr. Kindinger was Director, Michigan Department of Agriculture. He has served in two other posts in that Department: Assistant Director from June through November 1981, and Chief, Marketing and International Trade Division from September 1979 to June 1981.

From 1970 through 1975, following active-duty military service in the U.S. Navy Reserve, Dr. Kindinger held several positions in the agricultural economics departments of Michigan State University, the University of Minnesota and Cornell University. From 1975 to 1979, he was Director, Commodity Activities and Research Division of the Michigan Farm Bureau. From 1981 to 1983, he was Assistant Director, Cooperative Extension Service at Michigan State.

Dr. Kindinger earned his Bachelor's and Master's degrees in agricultural economics from Michigan State in 1970 and 1971, respectively, and a doctorate in agricultural economics from Cornell in 1975. He is widely published. His articles and research papers, most of them focusing on farm marketing, and pricing and profitability, have appeared in academic, trade and general news publications.

Dr. Kindinger has served in many volunteer posts associated with state, national and international agricultural and rural development issues. In recent years, he has been vice-president and president-elect (at the time of his USDA appointment) of the National Association of State Departments of Agriculture (NASDA); co-chairman of the Michigan Governor's Task Force for Revitalization of Agriculture through Research and Education; a member of the NASDA, U.S./Canadian Accord; member of NASDA policy committees including Marketing and Rural Development, Land Use, Natural Resources, and Environmental Quality, and Diary and Animal Health; president and vice president of the Midwest Association of State Departments of Agriculture; chairman of the Governor's Conference on the Future of Michigan Agriculture; and president of the executive committee of the board of directors of the Midwest International Agricultural Trade Council.

A Michigan native, Dr. Kindinger was born November 5, 1946, and grew up on his family's dairy, hog and cash crop farm in Reading, Michigan. He and his wife, Carol, and family now live in the Washington metropolitan area.

OFFICE OF PUBLIC AFFAIRS
Statement of Dr. Paul E. Kindinger, Director
before the House Subcommittee on Rural Development, Agriculture, and Related Agencies

Mr. Chairman and members of the subcommittee, thank you for inviting me to discuss the 1991 fiscal year budget request for the Office of Public Affairs (OPA).

OPA serves as the principal USDA contact point for dissemination of consistent and timely information to the public, the media, State and local governments and the agriculture industry. We provide leadership, expertise and counsel for the development of public affairs strategies.

The Office of Public Affairs was established by the Secretary of Agriculture on October 1, 1989. OPA retains two of the three functions performed by the former Office of Governmental and Public Affairs--Public Affairs and Intergovernmental Affairs. The Office of Congressional Relations (OCR) now reports to the Assistant Secretary for Congressional Relations. Funding for OCR is provided as part of the appropriation request for the Office of the Secretary.

The responsibilities of the offices in OPA are now re-defined as follows:

Office of Intergovernmental Affairs (OIA): USDA liaison for State and local governmental officials including Indian Tribal Councils, and the White House Office of Intergovernmental Relations.

Office of Publishing and Visual Communication (OPVC): Plans, produces and distributes all print and video information materials. OPVC provides centralized services financed through the Working Capital Fund for video production, teleconferencing, design, exhibits, photography, printing and publishing.

Office of Press and Media Relations (OPMR): Directs information programs targeted to radio, television and print media.

Office of Public Liaison (OPL): Develops and maintains liaison with the food and agriculture industry, and trade and consumer associations or other specialized interests seeking interaction with USDA.

Office of Programs and Planning (OPP): Responsible for strategic planning of new public affairs programs, coordination of issues teams and reviewing existing public affairs programs.

PLANS FOR 1991

The Office of Public Affairs will continue several of the traditional activities such as publishing the Yearbook of Agriculture, meetings with constituent groups, interaction with State and local governments, Native American programs, etc. Additionally, however, we will seek to expand our outreach to minority populations through radio and printed material. OPA has also formed several Public Affairs Issue Teams that are charged with designing and implementing public information programs about key issues. Examples of these cross-cutting issues are food safety, water quality, animal welfare, rural development, and biotechnology. These issues are ones that the public is demanding to know more about. The teams bring policy experts and public affairs personnel together in a unique way so that more complete, accurate information, from a variety of perspectives can be provided in a timely fashion.

In addition, we will be working hard in fiscal year 1991 to explain the results of two major activities facing us in fiscal year 1990, mainly the Farm Bill and General Agreement on Tariffs and Trade. Once both of these activities are completed by Congress, there is still a great deal of work to do. We must explain the probable impact on various interest groups.

Besides these challenges we are improving the management and overall operation of OPA. Our goal is to foster more innovative, efficient ways to meet the Public Affairs needs of USDA and its supporting agencies.

FISCAL YEAR 1991 BUDGET REQUEST

The fiscal year 1991 budget request is $8,882,000, an increase of $389,000 over the fiscal year 1990 appropriation. We are requesting an increase for increased operating costs to cover inflation, e.g., communications, printing, supplies and other services and for mandated pay raises.

This concludes my statement, Mr. Chairman, I will be happy to answer any of your questions.

OFFICE OF PUBLIC AFFAIRS

Purpose Statement

The Office of Public Affairs (OPA) was established by the Assistant Secretary for Administration on October 1, 1989, under the delegated authority contained in 7 CFR, Part 2.25, and the authority contained in 5 U.S.C. 301 and the Reorganization Plan No. 2 of 1953 (7 U.S.C. 2201).

The Office of Public Affairs retains two of the three functions performed by the old Office of Governmental and Public Affairs--Public Affairs and Intergovernmental Affairs. The third function, Congressional Relations, was transferred to the Office of the Secretary under the same delegation of authority that created OPA.

The Office of Public Affairs provides leadership, expertise, and counsel for the development of public affairs strategies which are vital to the overall formulation, awareness, and acceptance of U.S. Department of Agriculture programs and policies. OPA serves as the principal USDA contact point for dissemination of consistent, timely information.

The two major programs are:

1. Public Affairs. Provides direction, leadership and balance in the development and delivery of useful information through all media to the public on USDA's involvement in all areas of agriculture, including: research, educational and regulatory activities; nutrition, conservation and farm programs; forestry and international agriculture. It also serves as the focal point for liaison between the Department and the public, including the many associations and companies representing America's food and fiber system, with emphasis on policy education.

2. Intergovernmental Affairs. Directs and coordinates all programs involving the implementation of USDA policies and procedures applicable to the Department's intra and intergovernmental relations.

The Office of Public Affairs also provides centralized services financed through the Working Capital Fund in the areas of video and teleconference, and design and exhibits. Other centralized services are provided by the photography, printing, and publishing unit. The agency is located in Washington, DC. As of September 30, 1989, there were 142 employees. Of this total, 133 were full-time permanent and 9 were other than full-time employees.

OFFICE OF PUBLIC AFFAIRS

Available Funds and Staff-Years

1989 Actual and Estimated, 1990 and 1991

Item	1989 Actual		1990 Estimated		1991 Estimated	
	Amount	Staff Years	Amount	Staff Years	Amount	Staff Years
Direct Appropriation...	$8,412,000	116	$8,493,000	125	$8,882,000	125
Obligations Under Other USDA /Appropriations:						
Consolidated Orders....	237,445	--	--	--	--	--
Agency Photo Service...	565,222	--	560,000	--	585,000	--
Electronic Dissemination of Information...	270,369	--	--	--	--	
Ag Journalist Conference............	187	--	15,000	--	15,000	--
Admin. Support to Working Capital Fund..	39,777	2	50,000	2	50,000	2
Total, Reimbursements..	1,113,000	2	625,000	2	650,000	2
Working Capital Fund:						
Video & Teleconference and Visual Design Services.............	3,616,000	23	3,635,000	26	3,729,000	26
Total, Working Capital Fund.................	3,616,000	23	3,635,000	26	3,729,000	26
Total, Other USDA Appropriations.........	4,729,000	25	4,260,000	28	4,379,000	28
Total, Agriculture Appropriations........	13,141,000	141	12,753,000	153	13,261,000	153
Non-Federal Funds:						
Sale of Photos & Slides	9,000	--	9,000	--	9,000	--
Total, Office of Public Affairs...............	13,150,000	141	12,762,000	153	13,270,000	153

Full-time Equivalent Staff-Years:	1989 Actual	1990 Estimated	1991 Estimated
Ceiling...............	141	153	153
Non-Ceiling...........	1	4	4
Total...............	142	157	157

OFFICE OF PUBLIC AFFAIRS

Permanent Positions by Grade and Staff-Year Summary

1989 and Estimated 1990 and 1991

Grade	1989 Headquarters	1990 Headquarters	1991 Headquarters
ES-6	1	1	1
ES-5	0	0	0
ES-4	1	2	2
ES-3	0	0	0
ES-2	0	0	0
ES-1	1	5	5
GS/GM-15	8	13	13
GS/GM-14	25	26	26
GS/GM-13	21	21	21
GS-12	17	18	18
GS-11	10	11	11
GS-10	---	--	--
GS-9	12	13	13
GS-8	3	3	3
GS-7	18	18	18
GS-6	3	6	6
GS-5	4	5	5
GS-4	4	5	5
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Ungraded Positions	5	6	6
Total Permanent Positions	133	153	153
Staff-Years:			
Ceiling	141	153	153
Non-ceiling	1	4	4
TOTAL	142	157	157

OFFICE OF PUBLIC AFFAIRS

CLASSIFICATION BY OBJECTS

1989 and Estimated 1990 and 1991

	1989	1990	1991
Personnel Compensation:			
Headquarters	$4,806,000	$5,360,000	$5,636,000
11 Total personnel compensation	4,806,000	5,360,000	5,636,000
12 Personnel Benefits..........	595,000	716,000	732,000
13 Benefits for former personnel.................	11,000	13,000	14,000
Total pers. comp & benefits...	5,412,000	6,089,000	6,382,000
Other Objects:			
21 Travel......................	92,000	100,000	107,000
22 Transportation of things....	9,000	8,000	9,000
23.2 Rental payments to others..	--	--	--
23.3 Communications, utilities, and misc. charges.........	547,000	574,000	634,000
24 Printing....................	808,000	754,000	811,000
25 Other services..............	990,000	760,000	727,000
26 Supplies and materials......	146,000	119,000	123,000
31 Equipment...................	156,000	89,000	89,000
Total other objects...........	2,748,000	2,404,000	2,500,000
Total direct obligations............	8,160,000	8,493,000	8,882,000
Position Data:			
Average Salary, ES positions.....	$77,947	$75,696	$81,050
Average Salary, GM/GS position.	$40,423	$41,353	$41,400
Average Grade, GM/GS positions...	10.84	11.02	11.04

OFFICE OF PUBLIC AFFAIRS

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

1 Office of [Governmental and] Public Affairs

[Public Affairs]

For necessary expenses to carry on services relating to the coordination of programs involving public affairs, and for the dissemination of agricultural information and the coordination of information, work and programs authorized by Congress in the Department, [$7,964,000] $8,442,000 including employment pursuant to the second sentence of Section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225), of which not to exceed $10,000 shall be available for employment under 5 U.S.C. 3109, and not to exceed $2,000,000 may be used for farmers' bulletins and not fewer than two hundred thirty-two thousand two hundred and fifty copies for the use of the Senate and House of Representatives of part 2 of the annual report of the Secretary (known as the Yearbook of Agriculture) as authorized by 44 U.S.C. 1301: Provided, that in the preparation of motion pictures or exhibits by the Department, this appropriation shall be available for employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225).

2 [Congressional Relations]

[For necessary expenses for liaison with the Congress on legislative matters, $542,000.]

3 [Intergovernmental Affairs]

For necessary expenses for programs involving intergovernmental affairs, and liaison within the executive branch, [$479,000] $440,000.

The first change in language is to change the name of the Office of Governmental and Public Affairs to the Office of Public Affairs. A reorganization dissolved the old Office of Governmental and Public Affairs and created the Office of Public Affairs in its place. This change makes appropriation language consistent with current organization structure.

The second change reflects the move of the Congressional Relations function from the Office of Governmental and Public Affairs to the Office of the Assistant Secretary for Congressional Relations. This transfer of functions was accomplished as part of the reorganization of the Office of Governmental and Public Affairs.

The third change merges amounts appropriated to two separate accounts into a single appropriation. The Rural Development, Agriculture and Related Agencies Appropriation Act, 1990 contained separate appropriation accounts for the Office of Governmental and Public Affairs.

The FY 1991 Budget proposes to reestablish a single appropriation for these activities, and identify each individual activity as a line item within the Office.

OFFICE OF PUBLIC AFFAIRS

Appropriation Act, 1990..	$8,985,000
Budget Estimate, 1991..	8,882,000
Decrease in Appropriation..	-103,000

Adjustments in 1990		
Appropriation Act, 1990......................	$8,985,000	
Activity transferred to the Assistant Secretary for Congressional Relations a/....	-542,000	
Activity transferred from the Office of the Secretary b/.............................. ..	+50,000	
Adjusted base for 1990....................		$8,493,000
Budget estimate 1991...........................		8,882,000
Increase over adjusted 1990.....................		+389,000

a/ Pursuant to the authority given to the Secretary, in the Reorganization Plan Number 2 of 1953, functions of the Office of Congressional Relations were transferred to the Assistant Secretary for Congressional Relations at the beginning of 1990. Actual transfer of funds of $542,000 was made at that time.

b/ Pursuant to the authority cited above, the press office function in the Office of the Secretary was transferred to this office at the beginning of 1990. Actual transfer of funds was $50,000.

SUMMARY OF INCREASES AND DECREASES
(On basis of adjusted appropriation)

Item of Change	1990 Estimated	Pay Cost	Program Changes	1991 Estimated
Public Affairs............	$8,072,000	+$288,000	+$82,000	$8,442,000
Intergovernmental Affairs.	421,000	+16,000	+3,000	440,000
Total Available.........	8,493,000	+304,000	+85,000	8,882,000

PROJECT STATEMENT
(on basis of adjusted appropriation)

Item of Change	1989 Actual Amount	1989 Actual Staff Years	1990 Estimated Amount	1990 Estimated Staff Years	Increase or Decrease	1991 Estimated Amount	1991 Estimated Staff Years
Public Affairs..	$7,740,000	112	$8,072,000	119	+370,000(1)	$8,442,000	119
Intergov. Aff.	420,000	4	421,000	6	+19,000(2)	440,000	6
Unobligated balance........	252,000	--	--	--	--	--	--
Total available or estimate....	8,412,000	116	8,493,000	125	+389,000	8,882,000	125
Transferred to the Asst. Secy for Cong. Rel.	+497,000	+7	+542,000				
Transferred from Office of the Secretary.....	-50,000		-50,000				
Total, appropriations........	8,859,000	123	8,985,000				

EXPLANATION OF PROGRAM

The appropriation for the Office of Public Affairs funds the activities established pursuant to the relevant sections of Secretary's Memorandum No. 1927, dated October 5, 1977, and the authority contained in 5 U.S.C. 301 and Reorganization Plan No. 2 of 1953 (7 U.S.C. 2201). The activities carried out are as follows:

--Public Affairs - Public Affairs provides leadership, expertise, and counsel for the development of public affairs strategies which are vital to the overall formulation, awareness, and acceptance of U.S. Department of Agriculture programs and policies. Public Affairs serves as the principal USDA contact point for dissemination of consistent, timely information.

--Intergovernmental Affairs - Directs and coordinates programs involving the implementation of USDA policies and procedures applicable to the Department's intergovernmental affairs and relations with other Departments.

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $370,000 for Public Affairs consisting of:

(a) An increase of $82,000 for increased operating costs.

Need for Change. These funds will enable the office to meet rising operating costs.

Nature of change. This increase will cover costs associated with inflation, e.g. communications, printing, supplies and other services.

(b) An increase of $177,000 for the 1989 pay raise and $111,000 which represents 50 percent of the 1991 pay raise. The remaining 50 percent of the 1991 pay raise and the total 1990 pay raise are being absorbed.

(2) An increase of $19,000 for Intergovernmental Affairs consisting of:

(a) An increase of $3,000 for increased operating costs.

Need for Change. These funds will enable the offices to meet rising operating costs.

Nature of change. This increase will cover costs associated with inflation, e.g. communications, printing, supplies and other services.

(b) An increase of $2,000 for the 1989 pay raise and $14,000 which represents 50 percent of the 1991 pay raise. The remaining 50 percent of the 1991 pay raise and the total 1990 pay raise are being absorbed.

GEOGRAPHIC BREAKDOWN OF OBLIGATIONS AND STAFF YEARS 1989, and estimated 1990 and 1991

	1989		1990		1991	
	Amount	Staff Years	Amount	Staff Years	Amount	Staff Years
Washington, D.C.	$8,160,000	116	$8,493,000	125	$8,882,000	125

OFFICE OF PUBLIC AFFAIRS

Status of Program

The Office of Public Affairs (OPA) provides useful information to the people of the United States, assuring that relevant USDA decision making processes are open to the effective expression of informed public viewpoints. To achieve that objective, USDA reports through the various media and sometimes directly to farmers, consumers, business interests, special groups, and the general public regarding the Department's programs, policies, and activities. The information arising from these programs is intended to provide basic information for the various publics served by USDA. The success of Department initiatives often depends on the effectiveness of public affairs programs in creating national public awareness, understanding, and acceptance.

Activities under this appropriation are carried out through two major program areas: Public Affairs and Intergovernmental Affairs.

PUBLIC AFFAIRS

Current Activities:

OPA serves as the Department's clearinghouse for providing the media with current information about USDA's programs and policies in the form of news releases, news features and photo features, background statements, speeches, report summaries and similar materials. OPA maintains continuous liaison with reporters, writers, editors, radio and television broadcasters, producers and specialized journalists. OPA monitors the activities of associations and organizations to assure appropriate information is available to USDA officials; and, assists in the preparation of briefing information for the White House and the Secretary.

In fiscal year 1989, OPA released 1,722 of the previously mentioned items for national distribution with most of those materials available both on paper as well as through electronic dissemination to reach a broader section of the public with greater speed.

OPA also works closely with the agencies and the Office of the Secretary in providing feedback to top officials on what the popular and trade press are saying about USDA programs, policies and actions.

"AG a.m.", a daily news digest that summarizes articles and editorials from newswires, national newspapers, news magazines and other key periodicals dealing with agriculture is prepared each weekday for nationwide early-morning distribution to Department officials and for electronic distribution to others interested in this service.

Both formal and informal training on how to deal with the media is provided to Department officials upon request, and coordination is routinely provided for top staff involved in news conferences, press briefings, and individual interviews.

USDA provides a variety of radio and television services to broadcast media:

RADIO--"USDA Radio News Service" is a 24-hour availability of 5 to 10 news items, many with voice actualities, each no longer than 60 seconds. These are recorded and made available at 5 p.m. EST each weekday except holidays. Participating stations pay a telephone toll to access the recording machines. Calls exceed 100 each day. A number of agricultural radio networks of up to 150 affiliated stations are regular users of this service.

In addition, four weekly series are offered on audio cassettes with accompanying cue sheets and are distributed to nearly 1,000 radio stations and networks. The four include "Consumer Time," five programs featuring food, marketing, clothing, pest control, gardening and related topics; "Agri-Tape", five programs including USDA News, Highlights, and interviews on major issues; "Agriculture USA," a 13-1/2 - minute documentary program covering a wide range of food and agricultural subjects aimed at the general public; and "News Feature Five," five new features which include research results and activities about a broad range of subjects.

Hispanic Information Service is a weekly service mailed to requesting stations. Offered on both audio-cassette and reel-to-reel tape, it contains at least four programs varying from 30 seconds to five minutes. It is voiced in Spanish with the content aimed at concerns of the Hispanic audience addressed by USDA and is currently provided to approximately 230 stations.

TELEVISION--"USDA Television News Service" provides weekly features including Department policy-makers and subject matter specialists. The items are distributed by satellite (Westar IV) Thursday evening and Saturday morning, and then repeated Monday morning. Feature subjects are wide range and include topics such as marketing, consumer interests, rural development, nutrition, conservation, forestry, environment, economics, production agriculture and international trade.

"Agriculture Update" is a bi-weekly 5-minute news format about farming production programs. "TV Research News Features" are 1 to 3-minute items produced on location and covering news developments in agricultural research. Also, television public service announcements are produced by or for USDA agencies periodically with OPA assisting in their distribution.

Various other public affairs services are available to the media and public. These include:

> PHOTOGRAPHS--OPA maintains the centralized USDA Photo Library of captioned black and white prints and color slides. These images illustrate the programs and activities of USDA agencies and cover subjects relating to agriculture, including food production, distribution, nutrition, marketing, safety, inspection, conservation, and research. OPA provides photographic research services and distributes photographs to the news media free of charge and to the public nominal for a fee covering the cost of reproduction. OPA and the National Agricultural Library are collaborating on a project to convert the Photo Library to optical disc storage. The first disc was released in December 1989. Discs will be available to agencies, universities, libraries, and the general public, thus increasing availability and use of USDA photographs.
>
> PHOTOJOURNALISM--OPA works with USDA agencies to develop and distribute to national and regional media picture stories and illustrated press releases to inform the public of USDA programs, activities, and services available.
>
> AUDIOVISUAL PRESENTATIONS--OPA works with USDA agencies to produce and distribute narrated slide presentations on various agricultural topics and programs. These are available as slide sets or videocassettes to educational organizations, industry, and the public for a nominal fee covering the cost of reproduction.

Selected Examples of Recent Progress:

A leader in electronic online dissemination of information, OPA continues to offer and expand computerized information delivery services for accessing USDA information by the news media and other publics. This information includes such items as national and regional news releases, economic and statistical reports, market reports, export trade leads, international agricultural trade summaries, agricultural research briefs, facts about agriculture, food and nutrition, and coming cultural events.

OPA administers to online services: One primarily for quick transmittal of USDA reports and news releases to other disseminators of agricultural information, especially electronic information services, and the other primarily for those interested in electronic access to a data base of information released recently by USDA.

OPA and National Agriculture Library (NAL) have taken the leadership in coordinating, planning and production of the first Department-wide optical compact disk--read only memory (CD-ROM) for librarians, researchers and others who want electronic access to dated information.

OPA serves as USDA's central coordinating unit for an ever growing number of requests filed by news media, individuals and groups for information under the Freedom of Information and Privacy Acts. Departmental regulations and guidelines are continually updated to conform with the law or new directives from the Department of Justice and Office of Management and Budget. The Computer Matching and Privacy Protection Act of 1988 has been implemented, including the establishment of Departmental Data Integrity Board which is chaired by the Director of OPA.

The number of calls to the radio daily Newsline service from January 1 through September 30, 1989 totalled 17,781. This compares to 17,661 during the same period in 1988. The number of news items on Newsline was 1,587, up 187 over the same period one year ago.

Television items transmitted via satellite for the January-September period totalled 626, compared to 341 one year ago. The television increase reflects a productive shift of personnel with the Division and acquisition of Betacam playback timecode facilities for each television producer.

A display booth for USDA Radio and Television was designed, constructed, and exhibited at the annual meeting of the Radio and Television News Directors Association. It is part of a Department-wide effort to inform broadcasters about the broadcast services offered by USDA. The booth will also be displayed at the annual meeting of the National Association of Farm Broadcasters.

A special project is underway in Television. "Agriculture - The Most Crucial Industry" has been written and shot. Editing is in progress. The 12-minute program reviews the importance of agriculture to the nation's economy and well-being.

The 1989 Yearbook of Agriculture--"FARM MANAGEMENT: How to Achieve your Farm Business Goals"--can help farmers make more successful decisions. This 336-page hardcover anthology of 65 chapters was released in November 1989. Chapters in it suggest where to get credit; when to invest in land or buildings; how to set goals; how to enter farming; what recordkeeping, accounting and budgeting systems are available; how to evaluate risk; how to choose among alternative farm enterprises.

One section focuses on the move toward sustainable agriculture and ways to combine the twin goals of maintaining environmental quality while succeeding in business. It covers other issues farmers face now, including global competition and biotechnology.

Experts from universities, the Cooperative Extension System and USDA--as well as farmers and others in the private sector--offer up-to-date information on management for beginning as well as sophisticated farmers. Case studies show real farmers facing real management decisions.

Two 50-State video conferences were produced by OPA this past year for the Extension Service. One honored the "75th Anniversary" of Extension Service and offered projections for the future. The second described new decision support computer system being used by State units around the country. Two other regional Extension video conferences were produced for audiences in Minnesota and North Dakota.

Secretary of Agriculture Clayton Yeutter held two live video conferences with TV news and farm reporters, and invited President George Bush to join him for two national radio news conferences with reporters using OPA's live teleconferencing capability. A total of 1,771 audio conferences were handled for USDA agencies in FY 1989, which exceeds FY 1988's high of 1,463.

Highlights in video production included features on "Biocontrol," "Alternative Agriculture," and "Agricultural Marketing Service: Pride and Shared Mission" as well as production services for USDA's weekly TV satellite news services and for a variety of video news releases highlighting work of the Agriculture Research Service.

A desktop publishing committee was established by OPA in FY 1989. This enables OPA to provide the leadership and development of standard formats for desktop publishing throughout the Department.

OPA provides centralized information coordination and management for the Department in the visual aspects of publications and exhibits.

OPA coordinates all Department exhibits at exhibitions, plus coordinate the shipping, set-up and dismantling of all travelling exhibits. The shipping and warehousing of national and international exhibits is also coordinated through OPA.

The following table provides workload data relating to the publications activity:

Publications Printed	FY 1988	FY 1989
Printing through main GPO or on contract	7,136	7,001
Miscellaneous orders placed through GPO's Rapid Response Center (RRC), GPO's Regional Printing Procurement Offices (RPPO), Federal Prison Industries (Unicor), and Commerce	2,077	2,135
Composition (In-House USDA)	390	570
Printing through USDA Duplicating Facility		
Miscellaneous orders placed through USDA Facility	77	115
Miscellaneous orders reviewed and cleared for printing in USDA Facility	913	918
Waivers for jobs not presented to OPA for clearance	3,443	3,997
Total Printing Orders	14,036	14,736

The above figures show an increase in orders of 700.

Publications Distributed

	*Popular Publications		All Publications	
	FY 1988	FY 1989	FY 1988	FY 1989
	(number of copies in millions)			
Total stock at start of year.......	4.82	4.15	7.20	6.60
New publications printed...........	.00	.10	4.95	6.76
Reprints and revisions printed.....	1.53	.52	3.18	2.31
Total available for distribution.	6.35	4.77	15.33	15.67
Stock disposed of..................	1.03	.17	1.46	.17
Stock at end of year...............	4.15	3.76	6.60	6.30
Total distributed..................	1.17	.84	7.27	9.20

*Includes Farmer's Bulletins, Home and Garden Bulletins, Leaflets, Fact Sheets, and Yearbook Separates.

Publications Reviewed

	FY 1988	FY 1989
New and Revised Manuscripts	531 a/	568 b/
Slight Revision and Reprints	115	139
Total Number of Reviews	646	707

a/ Includes 133 issues of periodicals
b/ Includes 111 issues of periodicals

Telephone Calls	FY 1989
Telephone calls for information/publications from Members of Congress.	6,043
Telephone calls handled by Visitors Information Center Staff.	54,000

INTERGOVERNMENTAL AFFAIRS

Current Activities:

The Office of Intergovernmental Affairs (OIA) maintains USDA liaison with State and local government officials including Indian Tribal Councils and the official organizations representing these officials and councils. Specifically, the Office of Intergovernmental Affairs responds to inquires and requests from State and local government officials either directly, or through the appropriate Government agency.

In the role of liaison, the Office of Intergovernmental Affairs solicits State and local evaluation of issues to be addressed by USDA and keeps State and local officials advised regarding current and pending Federal actions which will affect agriculture and rural America.

Selected Examples of Recent Progress:

OPA continued to serve as the Department's representative in talks dealing with the Commonwealth of Guam, Interior Department, and Defense Department to seek out ways to minimize the impact of the brown tree snake on Guam's economy.

OPA served on the Department's 1989 Drought Task Force and prepared biweekly drought status reports for distribution to agencies of the Department, the White House, Members of Congress, individual States, and the media.

OPA participated in the annual and regional meetings of the National Governors' Association, Council of State Governments, National Association of State Departments of Agriculture, and National Conference of State Legislatures.

OPA received and disbursed to appropriate agencies for their action NASDA Resolutions. Their responses were sent back of OIA for consolidation and clearance by OGC in time for NASDA's mid-year meeting.

OPA continued to maintain close working relationship with Indian Tribal Councils and the official organizations representing these officials and councils.

WEDNESDAY, MARCH 21, 1990.

OFFICE OF THE GENERAL COUNSEL

WITNESSES

ALAN CHARLES RAUL, GENERAL COUNSEL

J. ROBERT FRANKS, DEPUTY GENERAL COUNSEL

JAMES P. PERRY, ASSISTANT GENERAL COUNSEL, NATURAL RESOURCES DIVISION

JEANNE M. STANEK, SPECIAL ASSISTANT TO THE GENERAL COUNSEL

STEPHEN B. DEWHURST, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

Mr. WATKINS [assuming Chair]. The subcommittee will come to order. We'll hear from the Office of General Counsel.

Mr. Raul, welcome. We appreciate having you here, and since your full testimony will be made part of the record please summarize your statement.

Mr. RAUL. Thank you.

INTRODUCTION

Mr. Chairman and members of the subcommittee, I am pleased to appear before you this afternoon to discuss the Office of the General Counsel's fiscal year 1991 appropriation request.

I am joined by Bob Franks, Deputy General Counsel; Jim Perry, our Assistant General Counsel for the Natural Resources Division; Jeanne Stanek, Special Assistant to the General Counsel for Budget Matters; and, of course, Mr. Dewhurst.

The Office of the General Counsel is the national law office serving the Department of Agriculture. As a freestanding USDA agency integrating all the Department's lawyers, OGC is well positioned to provide independent legal services to the Secretary of Agriculture and each of the Department's 38 agencies and offices.

FY 1991 BUDGET REQUEST

For fiscal year 1991, we are requesting $23.5 million in direct appropriations. Of the almost $2 million increase, 63 percent, or $1.3 million, is for increases in pay rates and other non-discretionary operating costs; $431,000 for a new program initiative of pre-decisional environmental legal services; $135,000 for completion of our office automation system; and $172,000 for personnel transfers within the office.

GENERAL COMMENTS

As you know, the basic question posed in all recent OGC budget testimony has been how to meet the burgeoning increase in demand for services while holding the line on spending.

Last year, we stated that over the past 10 years the number of legal matters, particularly cases, referred to our office has increased 350 percent, while our major resource, our people, has increased only 12 percent.

To demonstrate the growth another way, the average number of cases for which each attorney was responsible grew from 54 to 176 over the same 10-year period.

Given our current responsibilities, our personnel resources are spread very thin. In fact, an informal survey we have conducted shows that USDA has the second lowest ratio of General Counsel staff to total program staff among all Cabinet departments, with only the Department of Veterans Affairs having relatively fewer lawyers. At the same time, USDA's legal work is among the most complex and diverse of any department.

There are several areas of our current work that I would like to highlight to demonstrate how OGC serves the Department in ways that go well beyond the processing of cases.

We have been involved in development and preparation of the Administration's 1990 Farm Bill proposals. As farm legislation moves through the Congress this year, we will continue to provide considerable legal advice, legislative drafting and analysis with regard to this legislation.

OGC greatly assisted Department officials in developing the Administration's policy on food safety regulation and legislation concerning pesticides and pesticide residues in food.

The steadily increasing prominence of agriculture in the international trade of the United States continues to magnify the demand for legal services in this area.

OGC has provided legal advice with respect to United States proposals on agricultural trade in the Uruguay Round of GATT negotiations, and this work is expected to accelerate as the Round approaches completion at the end of 1990.

We have also been actively involved in a significant number of GATT dispute settlement proceedings involving agricultural commodities and products.

In addition, I have recently obtained authorization from the Department of Justice for our attorneys to represent the Department's interests in a limited number of natural resource appeals each year before the Federal Courts of Appeals.

I believe this will enhance the ability of OGC attorneys to bring our client specific knowledge to bear on these cases at the appellate level, as well as to sharpen our legal analysis of issues that will have a significant impact on our clients.

PRE-DECISIONAL ENVIRONMENTAL LEGAL WORK

Now I would like to turn to the specifics of our budget. I am requesting an increase of $431,000, which corresponds to 13 staff years, in order to enable us to perform substantial pre-decisional environmental legal work for the Forest Service.

The Department's management of National forests has been seriously disrupted by adverse judicial decisions, litigation and administrative appeals involving environmental issues.

The Forest Service's decisionmaking has been challenged in recent years under numerous statutes enacted in the past two decades to protect environmental quality.

The environmental challenges are often based on the agency's allegedly inadequate documentation of its decisions. Litigation losses have resulted in declines in timber sales and delays or cancellation of development of recreation sites, roads, land exchanges, mining and mineral leasing, and other programs.

We believe that the best strategy for the Department is to form national teams to provide significant pre-decisional legal services to the Forest Service, especially on critical policy initiatives and projects.

The most valuable contribution that OGC can make to the defensibility of agency action is early involvement in the preparation of environmental and decision documents.

Right now, OGC is for the most part only able to respond to the Forest Service's legal needs in the environmental law and administrative decisionmaking area by providing post-decisional legal services when a dispute arises.

However, a largely post-decisional practice is just not effective in the current state of environmental law and jurisprudence.

The number of administrative appeals of Forest Service decisions has dramatically escalated in the past five years from 439 in 1984 to 1,291 in 1989.

Under current statutes, a single case can have devastating program consequences. This is best illustrated by the broad programmatic injunction issued in the spotted owl case, which involved 168 timber sales.

This new preventive law strategy cannot be absorbed within existing resources. The pending caseload precludes the attorneys currently assigned to Forest Service work from participating substantially in pre-decisional planning activities.

Therefore, we are requesting approval of this modest increase that would permit us to add 10 attorneys and three support staff.

OFFICE AUTOMATION

I'm very happy to report that the office automation efforts initiated over the past two years have been effective and are beginning to be of great help to us every day.

With the assistance of this committee and Congress, we have procured and installed a major portion of our integrated officewide automation system.

Now we are beginning the development and design of the final phase of the system, internal case tracking, work measurement, archival and other record keeping capabilities. However, we cannot afford to finish this year. Completing this computer enhancement for OGC is not, in my opinion, merely optional or marginal. It is essential for us to get a handle on our job. Right now, we simply have no accurate and readily accessible means of tracking cases and other legal matters pending in the office. Without this ability, thoroughly responsible management of OGC is very difficult. Therefore, we are requesting a net increase of $135,000 to complete OGC's computer needs.

PERSONNEL TRANSFERS

A small but important increase is $172,000 for personnel transfers within the office. In the past, we have been generally unable to afford transfers of personnel among our offices.

With the new regional structure we implemented last year and our efforts to become an integrated national law office, the ability to transfer personnel has become essential to the management of this office.

This increase will allow us to manage our personnel resources more effectively and provide more diverse work experiences for our staff.

INCREASED OPERATING COSTS

By far, the largest portion of our request is to cover standard increases in day-to-day operating expenses—the increasing cost of doing business—over which we have no control.

Specifically, there are $1.1 million for pay costs and $202,000 for inflation. Because our budget consists primarily of funds for personnel compensation, we have no way to absorb inflationary and pay rate increases other than to reduce our staff. Therefore, these funds are essential to our financial situation.

CLOSING

The budget request for fiscal year 1991 is a prudent one that will allow us to fund the 1990 level of legal services in 1991, to provide more emphasis to environmental issues, to move toward becoming a more unified national law office, and to better discharge our responsibility as the legal arm of the Department.

That concludes my statement, Mr. Chairman. We certainly appreciate the support this committee has given us in the past. I would be happy to answer any questions you and the subcommittee members may have at this time. Thank you.

[CLERK'S NOTE.—Biographical sketches appear on pages 73 through 74. The prepared statement of Mr. Raul appears on pages 75 through 85. The explanatory notes appear on pages 86 through 107.]

STAFFING LEVEL

Mr. WATKINS. I don't have too many questions, but I notice you have approximately 242 attorneys and 145 support staff. Has that been an increase in the last year?

Mr. RAUL. Well, that represents our authorized level, Mr. Chairman. We are making an aggressive effort to hire up to our ceiling.

We have, at this point, about 10 vacancies for attorneys in Washington and in the field, but we are moving close to that authorized level which you referred to, and I have an aggressive campaign to try and bring those attorneys and support staff on board so we can handle the legal responsibilities we have.

GROWTH OF CASELOAD

Mr. WATKINS. The case load you say has grown from 54 to 176 over the same period of time you're talking about. Does that include all these liquidation cases and the farm situation?

Mr. **Raul**. That's exactly right, sir. The bulk of that caseload, approximately 31,000, represents Farmers Home Administration civil litigation, and it is in the nature that you referred to.

OUTSIDE COUNSEL

Mr. **Watkins**. Are you using a lot of outside counsel? What level of resources are being directed for use in retaining outside counsel?

Mr. **Raul**. Well, we have just instituted with Farmers Home Administration a program, which was authorized in legislation in 1988, of using outside counsel to handle some rural housing cases.

That program is really just underway, and under it, we work cooperatively with Farmers Home Administration. The program now is in three States, and we're contemplating adding, I believe, several additional States.

The outside counsel are actually retained by Farmers Home Administration, so I don't have with me the dollar amount that is being used for that, but I can provide that for the record, if I may.

[The information follows:]

PRIVATE ATTORNEY CONTRACTS

The Farmers Home Administration selected three counties for the first private attorney contracts: one county each in Ohio, Illinois, and Wisconsin. Bids on those contracts ranged from $600 to $1,000 per case for attorneys' fees. Cases have been assigned to the contractors in all three counties: 24 in Ohio, six in Illinois, and 18 in Wisconsin. To date, seven foreclosures have actually been completed—all in Wisconsin. In all three locations, the contractors have filed complaints in all but two of the assigned cases. No problems with this foreclosure process have emerged in these locations.

FmHA has further authorized its State Directors in the following States to use this authority provided they can document it is cost-effective and will shorten the time it takes to foreclose compared to other means: New Jersey, Louisiana, Puerto Rico, Idaho, Ohio (remainder of State), Hawaii, South Dakota, Arizona (two counties), and Florida (four counties). These States are in varying stages of making their initial determinations and soliciting bids, but no awards have been made yet.

Mr. **Raul**. But it is, as I say, a new program with the three States only recently becoming effective, so it's rather early to say what effect that will have and what the costs ultimately will be.

Mr. **Watkins**. Okay. Mr. Skeen?

Mr. **Skeen**. Thank you, Mr. Chairman.

ATTORNEY RECRUITMENT

Mr. Raul, welcome. You mentioned you're expanding your legal staff. What kind of flexibility do you have in starting salaries? I'm assuming that most of these are younger lawyers.

Mr. **Raul**. Yes, sir, Mr. Skeen. We don't have very much flexibility at all.

Mr. **Skeen**. That's what I wanted to know, to get an idea of just how competitive can you get.

Mr. **Raul**. Well, we do get some excellent attorneys, and we're now engaged in a recruitment program that really takes us to law schools throughout the country, many from agricultural areas, and we get a really good crop, if you will, of incoming law students that will start next fall.

But as far as trying to attract them with a starting salary, we're not that competitive. We hire attorneys at an entry level of GS-11, which is approximately $29,000, and given the private sector competition in, let's say a city like Washington, that is not a competitive salary.

On the other hand, we believe that our office and working for the United States Government offers other compensations, which is to say more interesting legal work, perhaps a higher degree of responsibility, and the satisfaction of having the United States Government as our client.

Mr. SKEEN. With as many attorneys as we're turning out of these law schools, you can also have one advantage, and that's volume.

Mr. RAUL. There are a lot of attorneys.

Mr. SKEEN. I say that puckishly, but I can see that you have a very difficult time, and there has to be some attraction to enter Government service, but I wish you well because that's going to be a very difficult situation.

GRAZING ADVISORY BOARDS

Mr. SKEEN. I have two questions dealing with the Forest Service. They deal with the Forest Service on Grazing Advisory Boards.

One of the questions is does the Chief of the Forest Service have the authority to create grazing advisory boards, and if not, would you please provide the current law that states he does not have this authority.

Also, in your opinion, does the Federal Advisory Committee Act provide the Chief of the Forest Service with the authority to create grazing advisory boards, and if not, why.

Mr. RAUL. The Chief has no specific authority to create grazing advisory boards. The Secretary of Agriculture has enjoyed specific authority to do so, most recently under section 403 of the Federal Land Policy and Management Act of 1976. However, that authority expired on December 31, 1985. The Secretary's regulation, 36 CFR 222.11, has not been utilized to appoint grazing advisory boards since the termination of the statutory authority.

While there is no specific law that says the Chief does not have authority to create grazing advisory boards, the Federal Advisory Committee Act and Title 18 of the Food and Agriculture Act of 1977 place authority at the Secretary's level to establish advisory committees. The Secretary has not delegated any authorities under the FACA to the Chief.

Mr. SKEEN. I appreciate your response and appreciate the job that you're doing.

I'm a little distressed at times, I notice that your new ground now covers environmental questions, and you've been challenged on the environment.

This seems to be a great hobby that's becoming more common throughout the United States today. Instead of doing something about the environment, we're choosing to battle it out in the courts, and I don't know that that's really progressive, but we'll leave that to history. Thank you very much.

Mr. RAUL. Thank you, Mr. Skeen.

Mr. SKEEN. Thank you, Mr. Chairman.

Mr. WATKINS. Mrs. Smith?

OGC STAFFING

Mrs. SMITH. In your testimony you mention an issue of major concern to this committee last year regarding the counsel's staffing. Last year and again this year, you mentioned that over the last ten years, legal cases involving the USDA have increased by 350 percent while staffing ~~has incr~~eased by 12 percent.

I know you believe that progress is being made on many cases; however, you predict an increase in future cases involving the Farmers Home Administration. Would you please explain further the current staffing difficulties you face and your caseload predictions? Are adequate resources being provided to keep up with the demands being placed upon the Department's legal staff?

Mr. RAUL. As I mentioned in my statement, I believe our staff is spread very thin. In Washington, we have major backlogs in the tort claims area and the reparations work under the Perishable Agricultural Commodities Act. Many other work areas are expanding, such as work related to international trade and the General Agreement on Tariffs and Trade. We are dealing with these situations by shifting staff responsibilities as best we can. We have also instituted an aggresive recruitment program to fill our existing vacancies and hire a pool of new law graduates.

With regard to our future caseload, it is very difficult to make accurate predictions. We do know that the Farmers Home Administration has about 45,000 new cases that may require litigation over the next couple of years. At the end of 1988, FmHA sent out notices to more than 75,000 delinquent farmer program borrowers. About one-half applied for loan servicing, for debt relief. Many did not apply for such servicing and, of course, some who did apply were found not to qualify. A number of these cases are currently in the FmHA appeals process. Based on information furnished by FmHA we understand that we may receive up to 36,000 new cases from this source during the remainder of this fiscal year and in fiscal year 1991. The volume of these additional cases will vary considerably by state. When the farmer program cases are added to the cases typically received on other programs, we recognize that the impact on our office will be substantial and can be expected to occur in the near future.

With regard to whether we have adequate resources to keep up with current and future demands for legal services, we would like to operate at our staff-year ceiling with the office automation system in place and obtain more firm data on projected caseload increases before assessing future staffing needs. However, we are closely monitoring the FmHA caseload situation and working with the agency to assess their legal needs and the urgency of meeting those needs.

ENVIRONMENTAL LITIGATION

Mrs. SMITH. Mr. Raul, you briefly mention that the USDA Counsel is beginning to get further involved in environmental litigation. In your testimony you used the example of cases involving the

Forest Service and cited the need to strategize federal legal efforts from various departments.

In light of the increasing attention given environment issues, would you further explain the importance of better organizing legal services? What are the advantages of such consolidation of efforts?

Mr. Raul. We have found that legal problems of the Forest Service and our other client agencies increasingly require coordination with numerous other federal and state entities. For example, the Alaska oil spill, which affected the Chugach National Forest, required negotiation and coordination with the State of Alaska, the Department of Justice, the Department of Commerce, EPA, and several agencies of the Department of the Interior. In Florida, we are assisting the Soil Conservation Service in negotiating a solution to agricultural runoff into the Everglades National Park, an effort which involves the Fish and Wildlife Service, EPA, the Corps of Engineers, the Department of Justice, and the Park Service. Further, both environmental groups and industry associations have organized their legal work at the national level. Thus, responses by the Forest Service to legal questions or administrative appeals on the 123 national forests must be uniform.

The Office of the General Counsel's proposal to establish teams of attorneys in principal problem areas will allow OGC to better utilize its experience and special subject matter expertise in assisting the Forest Service in avoiding litigation and improving defensibility of project decisions, thereby avoiding cost delays and judicial orders requiring revision of forest plans and environmental documents. The teams would assist the agency in drafting key regulations, directives, and EIS's, provide training to key client agency personnel on important legal issues, coordinate issuance of legal advice and opinions to assure uniformity between Washington and field offices, and make early determination of legal strategy on major lawsuits.

COMPUTER AND EQUIPMENT UPGRADE

Mrs. Smith. Last year, you were appropriated less than half of the amount you requested to purchase and install an office automation system. In addition, I realize that your budget requests $647,000 for additional equipment and office automation.

How much of the system has been purchased and installed at this time? What additional resources are needed to complete this system? How would your operations benefit?

Mr. Raul. As I said in my statement, with the increases appropriated in 1989 and 1990, we have purchased 337 personal computer workstations for both legal and support staff, linked our offices with an elementary telecommunications system, and purchased local area networks to allow each of our field offices to operate as an integrated unit. We are beginning the development and design of the final phase of the system—internal casetracking, work measurement, archival and other recordkeeping capabilities.

Office automation will go a long way to allow the office to act as a national law office rather than 23 separate uncoordinated units. When completed the system will provide faster word processing, electronic sharing of documents, recordkeeping, increased access to computerized legal research, and telecommunications among our 23 offices and between our offices and our client agencies, and outside agencies such as the Department of Justice.

I will provide more specifics for the record.

[The information follows:]

The system being installed will result in:

1. Sophisticated word processing capability including many features specifically designed for law office use. This will be available to all personnel and will increase productivity by eliminating retyping and facilitating reuse of documents.
2. Network capability that provides document sharing and enhanced communications throughout OGC. This will allow sharing of expensive resources such as laser printers and access to modem pool for communication to other OGC locations, Department of Justice, client agencies, legal research services, etc.
3. Increased quality of end product by allowing more time to be spent on analysis and less time on the mechanics of document preparation. Availability of electronic spell checking, thesaurus and grammar checking will improve the quality of documents.
4. Data base management to provide a centralized casetracking system, correspondence control, and document and opinion archiving so that duplication of work can be substantially eliminated, caseload can be better managed, correspondence and other inquiries can be answered faster without "reinventing the wheel", and budget and other statistics can be gathered electronically and automatically.
5. Increased morale by reducing the amount of repetitive work and allowing the staff to spend more time on creative endeavors.
6. Ability to attract more qualified employees who have been exposed to advanced automation capabilities in law school, private sector law firms and other government agencies.

Mr. **Watkins**. Mr. Akaka?

Mr. **Akaka**. Thank you very much, Mr. Chairman.

RECRUITMENT PROGRAM

Mr. Raul, I was just reading your bio here, and I'm impressed when anybody can come out of both Yale and Harvard. I'm interested in your recruitment program.

You've initiated that to fill vacancies up to the authorized ceiling of 242 attorneys. How successful have you been to date on fulfilling that?

Mr. **Raul**. We have, as I mentioned, an aggressive recruitment campaign. I have established recently, since I joined the office, a recruitment committee that has been active in going out to law schools and interviewing on campus so that the fact that we are seeking attorneys to join our office is known to the law students. I'm pleased to report that for the graduating class of 1990, we made 21 offers, and 13 were accepted.

I believe that for any law office that's an outstanding ratio of offers and acceptances, and I believe that the candidates that we've made offers to and those that have accepted are really going to be first rate young attorneys.

So I'm very pleased with the results of our recruitment effort.

Mr. **Akaka**. I don't know whether this has any bearing on it, but what is the starting salary?

Mr. **Raul**. The starting salary, Mr. Akaka, is a GS-11, at approximately $29,000. So I believe that we're attracting these attorneys based on the opportunities that the office, the Federal Government, and being in public service have to offer.

CASELOAD PER ATTORNEY

Mr. AKAKA. What is the current case load per attorney?

Mr. RAUL. We have a statistical reference to that, and it works out to about 176 cases per attorney. Now, that isn't to say that each attorney has that many cases.

Some have many more, and some have fewer. Not all of our attorneys are involved on the litigation side. The attorneys that are in the field offices and working on Farmers Home Administration matters have many more cases than that.

Of course, the cases differ in complexity. For example, with respect to major environmental cases, while an attorney may be handling only one or two or three of those cases, in fact, they are very complicated and very demanding.

So that 176 number that I referred to is a statistical abstract, and some attorneys will have many more and some relatively fewer.

PRE-DECISIONAL LEGAL SERVICES

Mr. AKAKA. You request an increase of $431,000 to perform pre-decisional legal services for the Forest Service. At present, who provides the legal counsel to the Forest Service to assist them in their decisionmaking?

Mr. RAUL. We do, Mr. Akaka. The problem is that we don't have the legal resources available at present to be as involved as I believe that we should be at the pre-decisional stage.

So our ability to provide legal services to the client is limited to those cases where really a problem has arisen. In other words, either a lawsuit has been filed or an administrative appeal or some other concrete legal problem has arisen.

That brings us in rather late in the day, and our ability to provide adequate legal counsel to avoid problems is severely restricted.

So the pre-decisional aspect of the legal service, I believe, is critical to improving our client's ability to make decisions that will withstand judicial scrutiny so that we will win more cases in litigation and fewer cases should result in litigation when it is established that the decisions are defensible.

So while we are in the position of providing that pre-decisional legal work at present, because of the limitations on our resources, we're not able to do as much of a job as really we should.

Mr. AKAKA. What is your estimate on savings in post-decisional legal costs by implementing this program?

Mr. RAUL. That's a very good question, sir. It's difficult to evaluate, and I believe that all that can be said, as implied by your question, is that there might be some savings, but I think the caseload is so great that it's no more than a theoretical possibility.

But I do believe that, if our pre-decisional legal counsel is effective, at some point we should begin to see fewer cases.

But we've got really more cases even at the post-decisional stage right now than can be handled comfortably.

Mr. AKAKA. Thank you very much for your responses.

I have no more questions, Mr. Chairman.

PRE-DECISIONAL ENVIRONMENTAL LEGAL SERVICES

Mr. Whitten. The largest program increase requested, $431,000, is for "pre-decisional environmental legal services." This appears to be an unusual approach. Do you know of other agencies that do this?

Mr. Raul. Pre-decisional legal advice is essential given federal environmental laws and today's litigious society. It is not an unusual approach. Complying with environmental laws after the decision delays congressionally mandated actions, frustrates fulfillment of environmental laws and adds administrative and legal costs to activities. Court judgments and orders overturning agency decisions undermine public confidence in federal agencies.

While we do not have specific information regarding all other federal departments, we do know, for example, that the legal offices of the Federal Highway Administration and Army Corps of Engineers are sufficiently staffed that they provide pre-decisional review for their client agencies of documents developed to comply with the National Environmental Policy Act. Pre-decisional legal advice is widely recognized by the private sector as the most effective method to assure compliance with environmental laws, minimize litigation risk, and succeed against legal challenges. Environmental audits by house counsel are standard procedure for all well-run businesses.

The pay-off for pre-decisional legal advice is considerable under the Administrative Procedure Act. Judicial review of agency decisions is on the agency record. Therefore, unless the agency record—prepared prior to the decision—demonstrates fulfillment of federal environmental legal requirements, there is a high likelihood of a court overturning the agency decision. Indeed, a common strategy of opponents of projects is to use their lawyers to document in the agency record the steps necessary for the agency to comply with an environmental law and then use that documentation in court.

Mr. Whitten. Please describe a specific example of where such a technique may have proved useful.

Mr. Raul. OGC attorneys were able to aid in the successful defense of two recent lawsuits through pre-decisional legal advice and review. In *Wyoming Wildlife Federation* v. *Davis* (USDC Wyo.), one of our lawyers assisted in preparation of the Environmental Assessment, Finding of No Significant Impact, and Decision Notice, that was upheld on judicial review by the Wyoming District Court. The road project on the Shoshone National Forest involved issues arising under the National Environmental Policy Act and Endangered Species Act. In *Donham* v. *USDA* (USDC Ill.), an OGC attorney helped the Forest Service prepare a new Environmental Assessment, Finding of No Significant Impact, and Decision Notice for certain timber sales on the Shawnee National Forest. National environmental groups and a local group had challenged the earlier decision notices and environmental documents prepared without legal assistance. After review of the new documents prepared with OGC assistance, the national groups chose not to sue and the government successfully defended against the local group's lawsuit.

OFFICE AUTOMATION

Mr. WHITTEN. Your budget request includes an increase of $135,000 to complete your office automation system. When do you anticipate the system will be fully operational? What cost benefits will this system provide?

Mr. RAUL. If we receive the full appropriation request for fiscal year 1991, we hope that the system will be fully operational by January of fiscal year 1992.

The Department of Justice's Civil Division has installed a system similar to ours which offers a personal terminal to every employee in selected offices. A study conducted by the Department of Justice determined that this system resulted in a benefit to cost ratio in excess of 2 to 1.

A similar study by the Forest Service of its office automation system, also designed to maximize access by all employees rather than simply automate secretarial tasks, estimated its benefit to cost ratio as 1.8 to 1.

Like the Civil Division, we, too, are a large legal office and, like the Forest Service, geographically dispersed. Accordingly, we can safely assume that our office automation will result in cost benefit ratios at least the same as those of the Department of Justice and the Forest Service.

Mr. WHITTEN. I noticed your object classification breakout included an increase of only $2,000 for equipment in fiscal year 1991. Does this mean that you do not need to purchase any more equipment for this system? What will your requested increase of $135,000 be used for?

Mr. RAUL. The $2,000 increase is for inflation on our non-ADP equipment budget. In fact, if our request is approved, we plan to spend $647,000 in fiscal year 1991. Five hundred twelve thousand dollars is for ADP equipment and is already in our base. The net increase of $135,000 is for operation of the system—specifically, telecommunications and computerized legal research line charges.

Mr. WHITTEN. Once the system is completed, what will it cost annually to maintain? Do you have the expertise within the Department to maintain the system or will you contract out for the maintenance?

Mr. RAUL. Because the Department does not provide maintenance services to the agencies, our fiscal year 1989 budget request included funds for an office automation manager who would generally maintain and update the system. We have filled the position at the GS–13 level for an annual cost of about $50,000.

Our present ADP procurement contract provides for technical support and equipment repair. At the present time, it is difficult to estimate the total annual cost of these services because they are performed on an "as needed" basis. However, our current operating plan includes estimates of $5,000 for technical support and $50,000 for repairs.

After we gain more experience under the system, we will reevaluate our needs in this area. It is anticipated that we may need at least one additional position.

Mr. WHITTEN. Please provide, for the record, a complete breakout of the total cost of the system.

Mr. **Raul**. I will provide that information for the record.
[The information follows:]

Total cost of office automation system

Permanent:	
Systems administrator	$50,000
Local area network line charges	75,000
Computerized legal research	250,000
Line charges for telecommunications	400,000
Rental of additional telephone lines	20,000
Replacement/upgrade	100,000
Research and development	75,000
Equipment maintenance	300,000
Training	75,000
Travel	20,000
Software development	25,000
Supplies	30,000
Subtotal	1,420,000
One time:	
ADP equipment, software and installation	2,748,528
Total, automation	4,168,528

PERSONNEL MATTERS

Mr. **Whitten**. On pages 6–8 of your explanatory notes, you request an increase of $431,000 to hire an additional ten attorneys and three support staff to perform pre-decisional environmental legal services for the Forest Service. How do you propose to hire 13 additional staff for $431,000 when the average salary for GM/GS positions is $41,107?

Mr. **Raul**. The additional staff were budgeted at the entry level grades. Specifically, seven attorneys were calculated at GS–11/1, three attorneys at GS–12/1, and three support staff at GS–5/1. The total for salaries and benefits is $406,000. In addition, we included $25,000 for travel.

Mr. **Whitten**. Your budget reflects a staff year increase of 14 in fiscal year 1991 over fiscal year 1990. What will the fourteenth staff year be used for?

Mr. **Raul**. Our appropriated account reflects an increase of 14 while the reimbursable account shows a decrease of one. Through fiscal year 1990, one of our permanent staff years in the Natural Resources Division will be used for timber sales work under a reimbursable agreement with the Forest Service. When the agreement expires, this staff year will revert to the Division's appropriated account and will be used for review and revision of timber sale contract forms and regulations.

WATER LAW MATTERS

Mr. **Whitten**. Part of your requested increase for pre-decisional environmental legal work will be used to coordinate water law matters in the west. Please expand further on this subject and be sure to include how much will be devoted to this initiative.

Mr. **Raul**. The Department of Agriculture is currently involved in more than 40 water rights adjudications in the western states, most of which were initiated by various state agencies or private parties. We are also participating in hundreds of similar administrative proceedings. Although several agencies of the Department are involved in some of the larger, state-wide adjudications, the primary interest of the Department in these cases is the protection of the National Forest System resources. OGC provides, through our national office and field offices, direct handling of some of these matters, litigation support to the Department of Justice on the others, and legal counsel to the Departmental agencies on all of them.

In addition to the water rights matters, the Department is becoming increasingly involved in water quality matters. Some of these arise from activities conducted by our client agencies, but most of them relate either to actions taken by private parties or other public entities on National Forest System lands or to issues generally affecting the agricultural and silvicultural constituencies of the Department.

As with the water rights matters, the legal services provided by OGC on water quality issues are most often in response to actions initiated by state or local governmental bodies or private parties or because of an identified need for assistance in the agricultural or silvicultural sectors. Accordingly, it is difficult to establish workload priorities and staffing requirements precisely. However, we estimate that about one staff year would be devoted to coordination of water matters. We plan to integrate the workload related to both of these areas of water law, water rights and water quality, into the coordinated delivery system of legal services to be provided by the additional attorneys. In this way, we will be better able to respond to the currently increasing requests for legal counsel and assistance, as well as respond to future needs.

CHANGE OF DUTY STATION

Mr. WHITTEN. You are requesting an increase of $172,000 to fund three changes of duty station. What will these three changes be?

Mr. RAUL. At this point, there is no way of knowing what specific changes of duty station might be required in fiscal year 1991. We do not have three specific moves in mind. However, in late fiscal year 1989 and early fiscal year 1990, the heads of three of our field offices retired. At least three other field office heads are eligible to retire. This is not to say that if that happened we would fill each of those positions with a person from another location, but having the transfer funds available would give the office more flexibility in that regard.

Mr. WHITTEN. How will three changes of duty station allow you to manage your personnel resources more effectively?

Mr. RAUL. In the past we have been generally unable to afford transfers of personnel among our offices. When managerial vacancies occur in our various offices, there is a tendency to look only to that geographic area for the replacement. Being able to transfer people would not only ensure that appropriate promotional opportunities are made available to all of our staff but also permit us to select the best possible candidate regardless of their location. Also, when staff attorney vacancies occur in our field offices, we now recruit locally. However, workload needs in a particular office can change and work that was handled in one office might be better handled in another. If we have an attorney in Washington or another field location with the expertise needed, we now cannot encourage a transfer unless the attorney is willing to pay his or her own moving expenses. Funds for a small number of transfers would allow us the flexibility to retain and shift expertise more readily.

FIELD OFFICES

Mr. **Whitten**. What benefits or cost savings, if any, resulted from the restructuring of your field offices?

Mr. **Raul**. Since the restructuring of our field offices did not involve closing or consolidating any offices, I do not believe that any cost-savings can be directly attributable to the restructuring. However, there are important management and professional benefits that have resulted from the restructuring. A significant benefit is improved coordination of legal work. To enhance the new restructuring, we have instituted a weekly activities report to the General Counsel from the Regional Attorneys and a weekly conference call with the Deputy General Counsel and others and the Regional Attorneys. These methods of communication have improved the coordination of legal work, resulted in less duplication of effort, and improved morale by making all offices feel more a part of a national law office.

Some of the purposes of the restructuring were to improve oversight, get a better handle on our workload—particularly our caseload—and permit more efficient use of personnel resources. We believe that more effective oversight and lines of responsibility have been established by making the Regional Attorneys directly accountable to the General Counsel, while the heads of smaller offices are directly accountable to the Regional Attorneys. With the five regional attorneys overseeing all of the other branch offices, they are able to help us better evaluate workload and identify where the greatest needs are. As a result, we have already had situations where an attorney in one office has been assigned to help on litigation in another. In the past, this would have been very difficult to assess and to accomplish.

ANIMAL AND PLANT QUARANTINE

Mr. **Whitten**. On page 6g-2 of your explanatory notes you state that you rendered legal advice concerning numerous issues, including *Salmonella enteritidis* in eggs and the Department's authority to take action under the animal quarantine and related laws. What advice did you give the Department regarding this issue?

Mr. **Raul**. We advised the Department that the Secretary of Agriculture has broad authority to take measures as he may deem proper to prevent the introduction or dissemination of communicable diseases of livestock or poultry and in some instances it must be a dangerous communicable disease of livestock or poultry or one which constitutes an emergency and threatens the livestock industry of the country. We advised the Department that until it could be shown that *Salmonella enteritidis*—SE—constitutes such a communicable disease of livestock or poultry, the provisions of the Animal Quarantine laws could not be used to address the problem of SE in eggs. Originally, the experts were not willing to conclude that SE was a communicable disease of livestock or poultry. Later, after further study, the Department concluded that SE was a communicable disease of poultry, and on February 16, 1990, published an interim rule in the *Federal Register*, at 55 F.R. 5576, which declared that the poultry disease caused by *Salmonella enteritidis* serotype *enteritidis* was a communicable disease of poultry in the United States and placed restrictions on the interstate movement of certain chickens, eggs and associated articles in order to prevent the spread of the disease.

RESEARCH AND PROMOTION PROGRAMS

Mr. **Whitten**. You've stated, on page 6g–3 of your explanatory notes, that you continue to assist in the collection of past due obligations to the Commodity Credit Corporation and Research Board. Please provide a ten year table, for the record, showing how much you spend toward each initiative versus how much is actually collected.

Mr. **Raul**. Attorneys in the Office of the General Counsel work with the staff of the Dairy Division, Agricultural Marketing Service, to collect past due obligations to the Commodity Credit Corporation under the dairy collection program and to the National Dairy Promotion and Research Board under the dairy promotion program. The Office of the General Counsel first received referrals in connection with both programs in fiscal year 1986.

Since that time, OGC has received 74 referrals from the agency representing $1,118,630.19 in unpaid assessments for the dairy collection program and 49 referrals from the agency representing $747,348.18 in unpaid assessments for the dairy promotion program. OGC has devoted to these programs an estimated .5 staff years or about $25,000 for each fiscal year beginning with FY 1986. OGC has referred 16 dairy collection cases and 13 dairy promotion cases to the Department of Justice for collection. Cases otherwise handled or disposed of, including issuance of prelitigation demand letters, have resulted in collection of $322,716.23 for the dairy collection program and $45,341.63 for the dairy promotion program.

I will provide a table for the record showing collections under the dairy collections and dairy promotion programs.

Fiscal year	Dairy collection program	Dairy promotion program
1986	$38,474.28	
1987	33,392.92	$1,851.22
1988	87,574.66	11,740.19
1989	91,243.30	5,654.15
1990 (March 25th)	72,031.07	26,096.16

USDA has closed 49 dairy collection cases and 23 dairy promotion cases. Many of the uncollected amounts in both programs involve business entities now in bankruptcy where prospects for collection of full amounts owed are minimal.

Mr. **Whitten**. Please update the table that appears on page 512 of last year's hearing record to include fiscal year 1989.

[The information follows:]

CCC FISCAL YEAR CASELOAD STATISTICS

Fiscal year	Cases referred	Value	Cases pending end of FY	Value
1984	1,841	176,300,000	3,089	191,100,000
1985	2,093	141,300,000	2,856	249,200,000
1986	1,948	100,700,000	3,874	307,900,000
1987	2,443	236,200,000	4,092	366,800,000
1988	1,446	199,400,000	4,237	447,500,000
1989	1,237	162,700,000	3,556	391,600,000

ANIMAL WELFARE ACT

Mr. **Whitten**. Your office has assisted APHIS in the drafting and review of regulations to implement the 1985 Improved Standards for Laboratory Animals Act. How much of your budget has been devoted to this issue? How much do you plan on spending in fiscal years 1990 and 1991?

Mr. **Raul**. Several attorneys have worked with APHIS in preparing the new regulations during the last four years. We have devoted a cumulative total of between .5 and .75 staff-years in each of fiscal years 1986, 1987, 1988, and 1989 on these regulations. We anticipate that we will spend approximately .5 staff-year on these regulations during Fiscal Year 1990. APHIS' timetable for the completion of this rulemaking contemplates publication of the final rule in the Federal Register in late September 1990. Unless unexpected delays occur, we anticipate expending only minimal resources on this matter in fiscal year 1991.

Mr. **Whitten**. Parts I and II of the regulations have been implemented. When can we expect Part III, whch deals with facilities and transportation standards, to be implemented?

Mr. **Raul**. Parts I and II of the regulations, which contain definitions, and requirements for licensing and registration, Institutional Animal Care and Use Committees, veterinary care, and humane handling of animals covered by the Act, were published as final rules on August 31, 1989, and became effective on October 30, 1989. Part III contains the standards for the humane housing, care, and transportation of animals covered by the Act. We will work with APHIS to conclude the Part III regulations as early as possible given the number of comments that are likely to be received on the proposal.

Mr. **Whitten**. Are there any more parts of the regulations to be worked on?

Mr. **Raul**. The promulgation of the revised Part III will conclude the regulatory revisions required by the 1985 Improved Standards for Laboratory Animals Act. As part of its regular review of the regulations, APHIS published in the April 5, 1990 issue of the Federal Register an advance notice of proposed rulemaking. In that document, APHIS requested comments regarding the possible development of standards designed specifically for the humane care of farm animals used for research, nonagricultural exhibition, or as pets.

HORSE PROTECTION ACT

Mr. WHITTEN. You have also provided legal services to APHIS in connection with the Horse Protection Act program in developing new regulations concerning the industry self-regulation program. Please explain in further detail what this program is?

Mr. RAUL. Congress amended the Horse Protection Act in 1976 to authorize the Secretary to establish and monitor a Designated Qualified Person program. Under this program, the management of each show at which Tennessee Walking Horses perform can hire a DQP to check every horse before it enters the show ring. To avoid being liable for permitting a sore horse to show, management prohibits the showing of any horse which the DQP finds is sore or otherwise in violation of regulations in the DQP handbook. Trainers whose horses are turned down by a DQP are subject to DQP program penalties in addition to any penalties prescribed for violations of the Horse Protection Act. DQP's must be licensed by an organization certified by the Secretary. There are currently five certified organizations whose rules must be approved by the Secretary. U.S.D.A. veterinarians attending a show monitor and report on the performance of the DQP.

In connection with the DQP program, APHIS recently has proposed revisions to the inspection procedures to be followed in the examination of horses. The propsoed rule was published in the Federal Register on March 28, 1990.

FARMERS HOME ADMINISTRATION

Mr. WHITTEN. In your testimony you state that, although there was a slight decrease in your civil litigation caseload in 1989 over 1988, you thought this trend was only temporary since you anticipate a substantial number of new cases in the Farmers Home Administration farm program loan area. Please provide for the record, the total number of cases there were in fiscal years 1988 and 1989 and the number of cases you estimate having in fiscal years 1990 and 1991. Also show, for each fiscal year, how many of these cases is in the farm program loan area.

Mr. RAUL. The total number of civil litigation cases handled by OGC in fiscal year 1988 was 56,112, of which 18,168 were closed. In fiscal year 1989 51,481 cases were handled and 16,993 were closed. Our estimate of cases to be handled in fiscal year 1990 is 58,488 and for fiscal year 1991 the number is 80,488. The figures for fiscal years 1990 and 1991 do not include an estimate of the cases to be closed each fiscal year. We cannot identify the portion of these cases received in fiscal years 1988 and 1989 that are farmer program cases since we do not record cases by agency program. The 1990 and 1991 estimates do include 12,000 farmer program cases in fiscal year 1990 and 24,000 of such cases in fiscal year 1991, based on estimates from data provided by FmHA indicating there will be referrals in these quantities during that time frame.

Mr. WHITTEN. What do you attribute this substantial increase in the farm program loan area to?

Mr. RAUL. The substantial increase in Farmer Program cases results from a period of several years when action to collect delinquent debt in this program was enjoined by a federal court. Also, debt relief provisions were enacted by Congress while the injunction was in effect. Agency actions to provide relief further delayed referral of these cases for collection action. Accounts not resolved through debt relief provisions, including those which have been in administrative appeals, are now being sent to our field offices by FmHA. We are advised that approximately 36,000 farmer program cases may be referred to OGC during the remainder of this fiscal year and in fiscal year 1991.

GATT DISPUTE SETTLEMENTS

Mr. WHITTEN. Please describe in some detail a few cases of GATT dispute settlement proceedings involving agricultural commodities and products you've been involved in.

Mr. RAUL. During the past year the Office of the General Counsel has been involved in some major General Agreement on Tariffs and Trade dispute settlement proceedings.

The European Community challenge to the validity of the GATT Section 22 waiver was a very important case. Section 22 of the Agricultural Act of 1933 established a procedure for the imposition by the President of fees or quantitative restrictions on imports of commodities found to be interfering with price support and certain other programs administered by the Department of Agriculture. This procedure has been used to impose fees or quotas on various commodities, such as dairy products, cotton, peanuts, and sugar. In order to maintain our Section 22 import quotas and fees and not be in conflict with our obligations under GATT, the United States obtained a waiver from the GATT Contracting Parties of certain of its GATT obligations. This last year the European Community challenged under GATT the U.S. import fees on refined sugar and import quotas on certain sugar-containing products which had been imposed under Section 22. The EC requested a GATT dispute panel to recommend that the United States withdraw the import fees and quotas and to provide "compensation"—in the form of compensatory adjustment of other import duties or restrictions—in the meantime. OGC attorneys worked closely with the United States Trade Representative to prepare and present the U.S. defense. The GATT dispute panel upheld the validity of the waiver.

During this past year OGC attorneys provided assistance in connection with Australia's challenge to the U.S. import quota on raw and refined sugar as it was being administered under a "headnote" in the U.S. tariff schedules. The headnote authorizes the President, under certain conditions, to establish a rate of duty, limited by a quota, on imports of raw and refined sugar. A GATT dispute panel ruled that the way the quota was being implemented was inconsistent with the GATT. The United States accepted this conclusion and has since been evaluating the options available to bring U.S. policies into conformity with GATT and yet avoid "unilateral disarmament" in the context of the Uruguay Round negotiations which are now being conducted.

Last year, the United States succeeded in persuading a GATT dispute panel to find that Canada's import quotas on ice cream and yogurt were in violation of GATT. Under GATT, a country which has a program in effect controlling the domestic production or marketing of a commodity may, in certain circumstances, control the importation of the like commodity and certain products processed therefrom to protect its program. The panel found that Canada, which maintains marketing quotas for raw milk, had not met all of the GATT's requirements. In particular, the level of ice cream and yogurt imports was minuscule and, therefore, not likely to render ineffective its restrictions on marketings of domestic milk, and the quotas were not shown to be necessary. In addition, the panel concluded that ice cream and yogurt do not compete directly with raw milk and, therefore, could not be subjected to any import restriction. OGC attorneys developed the argument for the U.S. challenge of the Canadian import quotas and participated in the GATT proceedings.

The United States challenge in 1989 to the oilseeds policy of the EC was a very important case. The case was initiated by the U.S. soybean industry under section 301 of the Trade Act of 1974 and, after the U.S. Trade Representative accepted the case, it was referred to the GATT for dispute resolution. OGC attorneys drafted a substantial portion of the two briefs submitted on behalf of the United States and participated in two presentations to the GATT dispute panel in Geneva this past summer.

Essentially, the United States case rested on two claims: first, that the EC policy of paying subsidies to its domestic oilseed crushers to induce them to purchase EC oilseeds in preference to U.S. soybeans violated the non-discrimination or "national treatment" provisions contained in Article III.4 of the GATT; and second, that the EC policy of paying subsidies which have increased EC oilseed production from minimal amounts to almost 12 million metric tons annually effectively impaired the value of tariff concessions granted by the EC to the United States during the Dillon Round on oilseeds and oilmeals.

The panel agreed with the U.S. on both counts and, last December, issued its opinion which recommended that the GATT contracting parties require the EC to reform its oilseeds system. The panel report suggested that the EC eliminate its discriminatory payments to oilseed crushers and suggested that such reform might also lead to a solution of the tariff impairment issue. The EC has accepted the panel report and has indicated that it will revise its programs by the crop year beginning in 1991 to conform with its GATT obligations.

RECRUITMENT

Mr. **Whitten**. Please describe for the Committee some of the problems you face when recruiting General Counsel staff.

Mr. **Raul**. One of our biggest challenges is to achieve and maintain over time a fully-staffed Office of the General Counsel. In meeting that challenge, we will be required to devote substantial resources to our recruitment effort in order to reach out, attract, and retain highly-qualified young attorneys, committed to government service, and representative of the diversity of the constituency served by the Department of Agriculture.

Mr. WHITTEN. Also, describe in further detail the recruitment program you have initiated. Does this program address the problems you just described?

Mr. RAUL. As I indicated, we have had a very successful recruiting campaign and are looking forward to the arrival of an excellent group of 13 attorneys from the 1990 class of law school graduates. We plan to repeat this recruitment effort on an annual basis to achieve our authorized staffing levels. Next year, we will again pursue an ambitious schedule of on-campus interviews at law schools and job fairs. We also plan to adopt several enhancements for our recruitment program next year. We hope to establish ongoing relationships with placement officials and student organizations at law schools throughout the country to better inform law students of the opportunities and challenges offered by the Office of the General Counsel. We have worked hard as well to increase the number of minority attorneys on our staff—both in recruiting to fill current vacancies, and in recruitment of law school graduates for entry-level positions—and plan to continue and to strengthen these efforts next year. We also expect to initiate an honors law graduate program which will provide two or three exceptional graduates with an intensive clerkship in our office. Finally, we are considering the establishment of a summer clerkship program. We fully expect that these activities will assure success in meeting our recruitment objectves.

FEDERAL CROP INSURANCE CORPORATION

Mr. WHITTEN. Please update the Committee on the status of the suspension and debarment of the crop insurance agents that were discussed in last year's hearing.

Mr. RAUL. Debarment action was completed against one agent on the basis of the agent's submission of false data to support yield guarantees. Two Managing General Agents were suspended pending the completion of criminal action. No further requests have been made to the Office of the General Counsel by the Federal Crop Insurance Corporation for suspension or debarment actions.

Mr. WHITTEN. Give an updated status of your work in this area during fiscal year 1989.

Mr. RAUL. The continued expansion of federal crop insurance because of provisions contained in the Disaster Assistance Act of 1988 and the rewriting of FCIC policies in order to obtain unformity across delivery systems has required extensive legal services. The Office of the General Counsel continued to draft and rewrite program regulations and contractual provisions to simplify and strengthen all aspect of the program ranging from producer participation to reinsurance and agency contractual relationships. The Office of the General Counsel has been involved in the collection of funds which should not have been disbursed. We devoted increased efforts to collections, payments, administrative reviews, and claims. At the end of fiscal year 1989, 284 cases involving claims by or against the Corporation totaling $97.3 million were pending in litigation. Increasing resources were required to review cases pending against reinsured companies even though FCIC was not named as a party since the ultimate payment of the judgment and the expenses of litigation is from FCIC funds.

FOOD STAMP PROGRAM

Mr. WHITTEN. Please update the table that appears on page 513 of last year's hearing record to reflect any changes and the addition of fiscal year 1991 estimates.

Mr. RAUL. We will update the table and provide it for the record.

[The information follows.]

FOOD STAMP PROGRAM—COST AND STAFF YEARS

	Fiscal year—		
	1989	1990	1991
Funds	$882,028	$892,129	$917.812
Staff years	15.95	16.30	16.05

Mr. WHITTEN. Your office has also been involved in the collection of funds which should not have been disbursed. Please provide a five year table showing the amount of funds that have been identified versus the amounts that have actually been collected.

Mr. RAUL. Fiscal years 1981 through 1985 are the only years for which Food Stamp Program quality control liabilities have been billed or collected. Pursuant to amendments enacted in the Hunger Prevention Act of 1988, liabilities for FY 1986 and subsequent years will be calculated on the basis of a new formula. I will provide for the record a table showing the quality control liabilities assessed for fiscal years 1981 through 1985 and the amounts collected for those periods. Actual collections took place subsequent to the fiscal years for which the liabilities were assessed. The collections column includes settlement amounts, some of which remain to be paid under agreed-upon payment schedules. The Department of Agriculture is continuing its collection efforts with respect to the approximately $275 million in liabilities for these years which have not been either collected or otherwise resolved.

[The information follows:]

Fiscal year	Amount billed	Amount collected
1981	$8,631,135	$1,356,868
1982	6,964,935	1,574,523
1983	7,083,240	1,408,150
1984	73,399,066	558,503
1985	[1] 201,168,802	299,390
Total	297,247,178	5,197,434

[1] Projected billings based on initial notification of liabilities to the states.

ATTORNEY POSITIONS BY LOCATION

Mr. WHITTEN. For the record, provide a table similar to the one provided last year that shows the number of attorneys within the Office of the General Counsel and where they are located.

Mr. **Raul**. I will provide for the record a table showing our attorneys by location.

[The information follows:]

Location:	*Attorney Positions*
Washington, DC	132
Albuquerque, NM	3
Atlanta, GA	13
Chicago, IL	5
Columbus, OH	2
Denver, CO	9
Harrisburg, PA	7
Hato Rey, PR	2
Jackson, MS	2
Juneau, AK	3
Kansas City, MO	8
Lincoln, NE	2
Little Rock, AR	7
Milwaukee, WI	6
Missoula, MT	5
Montgomery, AL	3
Ogden, UT	4
Portland, OR	8
Raleigh, NC	2
Richmond, VA	2
San Francisco, CA	12
Stillwater, OK	2
Temple, TX	5
Total	244

ATTORNEY HOURS BY CATEGORY OF WORK

Mr. **Whitten**. On page 499 of last year's volume you provided a table of attorney hours worked for the previous fiscal year that broke out the categories of work for the attorneys. Please provide a similar tagble for fiscal year 1989.

Mr. **Raul**. The breakdown of hours worked by OGC attorneys by category for fiscal year 1989 will be provided for the record.

[The information follows:]

Attorney Hours Worked—Fiscal Year 1989

Areas:	*Hours*
Administrative Cases	54,298.5
Civil Cases	118,953.5
Criminal Cases	4,702.5
Nonjudical Foreclosures	5,923.0
Hearing Officer/Claims Adjudicator Cases	9,113.0
Regulations	21,103.5
Correspondence/Documents	85,013.0
Oral Opinions	44,211.0
Draft or Review, Legislation, Legislative Reports, Testimony	5,689.0
Other	62,356.5
Total	411,363.5

Mr. **Whitten**. Please provide, for the record, a table by program area showing the number of cases pending as of the end of fiscal years 1988 and 1989 and the current pending.

Mr. **Raul**. I will submit it for the record.

[The information follows:]

Cases pending as of September 30, 1988

[By agency]

Agricultural Marketing Service	747

Agricultural Research Service	45
Agricultural Stabilization and Conservation Service	4,627
Animal and Plant Health Inspection Service	814
Commodity Credit Corporation	263
Farmers Home Administration	33,355
Federal Crop Insurance Program	562
Federal Grain Inspection Service	16
Food and Nutrition Service	935
Food Safety and Inspection Service	187
Foreign Agricultural Service	6
Forest Service	3,346
Office of the Inspector General	16
Office of Transportation	8
Packers and Stockyards Administration	240
Rural Electrification Administration	10
Soil Conservation Service	274
Total	45,451

Cases pending as of September 30, 1989

[By Agency]

Agricultural Marketing Service	567
Agricultural Research Service	38
Agricultural Stabilization and Conservation Service	4,603
Animal and Plant Health Inspection Service	618
Commodity Credit Corporation	113
Farmers Home Administration	30,391
Federal Crop Insurance Program	458
Federal Grain Inspection Service	17
Food and Nutrition Service	791
Food Safety and Inspection Service	171
Foreign Agricultural Service	6
Forest Service	2,856
Office of the Inspector General	17
Office of Transportation	1
Packers and Stockyards Administration	206
Rural Electrification Administration	7
Soil Conservation Service	260
Total	41,120

Cases pending as December 31, 1989

[By Agency]

Agricultural Marketing Service	584
Agricultural Research Service	38
Agricultural Stabilization and Conservation Service	4,428
Animal and Plant Health Inspection Service	697
Commodity Credit Corporation	106
Farmers Home Administration	30,141
Federal Crop Insurance Program	441
Federal Grain Inspection Service	17
Food and Nutrition Service	763
Food Safety and Inspection Service	161
Foreign Agricultural Service	5
Forest Service	2,822
Office of the Inspector General	15
Office of Transportation	3
Packers and Stockyards Administration	206
Rural Electrification Administration	4
Soil Conservation Service	263
Total	40,694

TIMBER SALES

Mr. WHITTEN. On page 6-2 of the explanatory notes you show obligations from the Forest Service for timber sales to be $33,344 in fiscal year 1989, $60,000 in fiscal year 1990 and zero in fiscal year

1991. Do these obligations involve work on a specific contract or a number of contract sales? Please describe in some detail the work you do for the Forest Service with regards to timber sales.

Mr. RAUL. The monies provided by the Forest Service in fiscal years 1989 and 1990 fund one attorney to provide legal advice to the agency and assistance to the Department of Justice in litigation and damage collection efforts arising from 2,284 defaulted Forest Service timber sale contracts. This unprecedented workload was generated by the economic downturn in the timber industry which began in the early 1980s. Approximately $230 million of $308 million in claims owed the United States remain in cases pending before the United States Claims Court, federal district courts, and the Agriculture Board of Contract Appeals.

Although a number of attorneys, both in the field and in the Washington, D.C. office, are also involved in timber sale default issues, the reimbursable agreement with the Forest Service was part of a coordinated effort to process this nonrecurring caseload. Initially, this two-year agreement with the Forest Service envisioned that much of the default work would be completed by the end of fiscal year 1990; the facts indicate it will take longer. Some of the delay is due to over 50 lawsuits being suspended pending a decision on the constitutionality of the United States Claims Court similar to that made on the federal bankruptcy courts some years ago. The issue has been briefed and argued before the Federal Circuit Court of Appeals and the Government is awaiting a decision in *Seaboard Lumber* v. *United States*.

OGC provides direct legal support to the Forest Service on virtually every aspect of the timber sale contracting process. This involvement begins at the sale preparation stage and continues through the administrative appeals process to ensure that timber sale offerings conform to the requirements of the National Environmental Policy Act and other federal statutes. Next, OGC represents the Forest Service before GAO on any bid protests filed by timber sale applicants. Following the award of a sale to the successful bidder, OGC provides advice to contracting officers on any problems of contract administration and enforcement. OGC represents the Forest Service before the Agriculture Board of Contract Appeals and assists the Department of Justice before the U.S. Claims Court concerning timber sale contract disputes. OGC provides assistance on many other aspects of the timber sale program which result in appeals and litigation, such as the small business timber sale set-aside program and timber sale export restrictions. OGC also assists the Department of Justice in defending the timber sale program from legal challenges based on inadequate land management plans, and violation of Endangered Species Act and other wildlife protection requirements. Pending cases involve the northern spotted owl in the Pacific Northwest and the red-cockaded woodpecker in the Southeast. Finally, the timber sale default problem led to many ancillary problems such as referrals to the Treasury Department for revocation of a surety's certificate of authority for failure to honor bonds, and bankruptcies of timber purchasers. OGC assists in referrals to the Attorney General concerning suspected collusive bidding as required by the National Forest Management Act and provides substantial support in the suspension and debarment of timber sale purchasers.

PATENT APPLICATIONS

Mr. WHITTEN. As in the past, please provide a list of applications for patents reviewed by the Office of the General Counsel during fiscal year 1989.

Mr. RAUL. I will be happy to provide that for the record.

[The information follows:]

Patent Cases
Inventor: ANKENY MD, Kaspar, Horton, Jr.
Title: automated tension infiltrometer
Case Number: received-fy89-5/30/89 isurf 1104 joint ARS Iowa State
Disposition: filed-10/20/88 sn 260,022

Patent Cases
Inventor: ARIFOGLU M, Marmer
Title: sequential oxidative and reductive bleaching in a multicomponent single liquor system
Case Number: ds 35, received-fy89-1/17/89
Disposition: filed-fy-89-1/19/89 sn 299,174

Patent Cases
Inventor: AROLA RA, Marks
Title: self-feeding wood chunker
Case Number: fs 1010, received-fy89-3/17/89 connors
Disposition: filed-fy89-3/20/89 sn 325,804

Patent Cases
Inventor: BARTELT RJ, Dowd
Title: aggregation pheromones of the driedfruit beetle, carpophilus hemipterus
Case Number: 6995 mb, received-fy89-11/25/88
Disposition: filed-fy89-11/25/88 sn 275,863

Patent Cases
Inventor: BARTELT RJ, Dowd
Title: aggregation pheromones of the nitidulid beetles carpophilus hemiterus, carpophilus lugubris, and carpophilus freemani
Case Number: 7021 cr, received-fy89-7/28/89
Disposition: filed-fy89-7/31/89

Patent Cases
Inventor: BEREMAND MN, Black
Title: an improved method for producing trichothenes and related materials
Case Number: 7024 cr, received-fy89-8/29/89
Disposition: filed-fy89-8/29/89 sn 400,306

Patent Cases
Inventor: BERKA TR, Haas
Title: genetically engineered microorganisms containing a gene segment coding for a lipase from rhizopus delemar
Case Number: B 88-9, sw received-fy89-6/30/89
Disposition: filed-fy89-6/22/89 sn 369,975

Patent Cases
Inventor: BHADURI S, Turner-Jones, Vachica
Title: a new medium for identification and isolation for virulent strains of yersinia enterocoliltica based on calcium response
Case Number: DS 34, received-fy89-1/24/89 prepared by OGC
Disposition: none

Patent Cases
Inventor: BOYETTE CD
Title: control of hemp sesbania with a fungal pathogen
Case Number: mb 6997 received-fy89-4/11/89
Disposition: filed-fy89-4/17/89 sn 338,680

Patent Cases
Inventor: BRANDON DL, Corse
Title: antibodies to cytokinins having a glycosylated isoprenoid side chain and immunoassay methods
Case Number: w 1044, received-fy89-4/5/89
Disposition: filed-fy89-4/6/89 sn 334,069

Patent Cases
Inventor: BRENNER RJ, Patterson, Pierce, Hult
Title: insect control system
Case Number: 7019 cr, received-fy89-6/29/89
Disposition: filed-fy89-6/29/89 sn 373,310

Patent Cases
Inventor: BREWER HL, Butler
Title: processes and apparatus for moving plant materials and containers useful therewith
Case Number: ds 7, received-fy89-1/9/89
Disposition: filed-fy89-1/12/89 sn 296,109

Patent Cases
Inventor: CADMUS MC, Slodki
Title: heat stable, salt tolerant microbial xanthanase and method of producing same
Case Number: 7023 cr, received-fy89-8/29/89
Disposition: filed-fy89-8/29/89 sn 400,316

Patent Cases
Inventor: CHEN YR, Robinson
Title: application of knowledge-based system for grading meat
Case Number: cr 7000, received-fy89-2/6/89
Disposition: filed-fy89-2/9/89 sn 308,220

Patent Cases
Inventor: CHRISTEN AA, Gibson, Bland
Title: production of taxol or taxol-like compounds in cell culture
Case Number: mb 6996, received-fy89-3/23/89
Disposition: filed-fy89-3/24/89 sn 327,493

Patent Cases
Inventor: COLUMBUS EP
Title: differential ginning process and apparatus
Case Number: ds 2 DIV, received-fy89-3/9/89
Disposition: filed-fy89-3/6/89 sn 320,638

Patent Cases
Inventor: CONNOLLY G
Title: plastic M-44 stake with threaded lock ring
Case Number: aphis adc received-fy89-5/1/89
Disposition: none

Patent Cases
Inventor: COX NA, Bailey
Title: introduction of bacteria in ovo
Case Number: ds 49, received-fy89-7/13/89
Disposition: filed-fy89-6/5/89

Patent Cases
Inventor: DANIELSON JD, Lewis
Title: multiple bandmill for making a plurality of sawlines in the same longitudinal direction
Case Number: fs 8414, received-fy89-3/21/89 connors
Disposition: filed-fy89-1/17/89 sn 297,786 patented-fy89-9/12/89 4,864,905

Patent Cases
Inventor: DICKENS JC
Title: grean leaf volatiles as synergists for insect pheromones
Case Number: mb 7015 received-fy89-5/30/89
Disposition: filed-fy89-5/31/89 sn 359,174

Patent Cases
Inventor: DOMELSMITH LN, Rousselle, Berni
Title: method for the reduction of endotoxin in cotton lint or dust
Case Number: FWC s 6982, received-fy89-11/2/89 sil
Disposition: filed-fy89-11/4/88 sn 274,721 patented-fy89-5/23/89 4,832,751

Patent Cases
Inventor: DOWD PF, Shen
Title: microbial detoxification of xenobiotics
Case Number: mb 7004, received-fy89-1/25/89
Disposition: filed-fy89-1/30/89 sn 303,327

Patent Cases
Inventor: DOWD PF, Wicklow, Gloer
Title: nominine, an insecticidal fungal metabolite
Case Number: 7005 mb, received-fy89-5/17/89
Disposition: filed-fy89-5/17/89 sn 353,363

Patent Cases
Inventor: ELBEIN AD, Tropea, Molyneux
Title: novel pyrrolizidine alkaloid
Case Number: w 1042, received-fy89-8/14/89 joint ARS U. of Tex
Disposition: filed-fy89-12/13/88 (by Tex.) sn 289,907

Patent Cases
Inventor: GASVODA DS
Title: device for regulating luminous flux of battery powered headlamp
Case Number: fs 1008, received-fy89-3/23/89 connors
Disposition: filed-fy89-2/1/89 sn 305,316

Patent Cases
Inventor: GUNDERSON DE
Title: method and apparatus for testing materials using strain and moisture sorption
Case Number: fs received-fy89-2/28/89 connors
Disposition: filed-fy89-3/30/89 sn 330,527

Patent Cases
Inventor: HAN YW, Clarke
Title: production of fructan (levan) polyfructose polymers using bacillus polymyxa
Case Number: received-fy89-8/25/89 joint ARS SPRI pd 88-27
Disposition: filed-fy89-8/14/89 sn 393,604

Patent Cases
Inventor: HARPER RJ, Ruppenicker, Sawhney, Lambert
Title: crossdyeable cotton fabrics with removable warp size
Case Number: sw ds 9, received-fy89-6/30/89
Disposition: filed-fy89-7/7/89 sn 376,479

Patent Cases
Inventor: HARRELL RC, Adsit, Hoffman, Mumilla, Slaughter, Pool
Title: robotic fruit harvester
Case Number: joint ARS U. of Fla., received-fy89-9/28/89 filed by U.
Disposition: filed-fy89-12/2/88 sn 279,198

Patent Cases
Inventor: HEILAND WK, Konstance, Craig Jr.
Title: automated excision of undesirable material and production of s starting material for restructured meat
Case Number: b 7033 ds, received-fy89-6/26/89
Disposition: filed-fy89-6/27/89

Patent Cases
Inventor: HOSTETTER DL, Puttler
Title: a multiple embedded nuclear polyhedrosis virus from celery looper with activity against lepidoptera
Case Number: mb 6988, received-fy89-3/2/89
Disposition: filed-fy89-3/7/89 sn 320,126 patented-fy90-3/27/90 4,911,913

Patent Cases
Inventor: INGLETT GE
Title: oat soluble dietary fiber compositions
Case Number: 7020 cr, received-fy89-6/28/89
Disposition: filed-fy89-6/30/89 sn 393,978

Patent Cases
Inventor: JOHNSON LA
Title: method to preselect the sex of offspring
Case Number: mb 7008 received-fy89-5/10/89
Disposition: filed-fy89-5/10/89 sn 349,669

Patent Cases
Inventor: KADAN RS, Ziegler, Jr.
Title: improved flan-type pudding
Case Number: ds 24, received-fy89-1/27/89
Disposition: filed-fy89-1/30/89 sn 303,328

Patent Cases
Inventor: KLESIUS PH
Title: hybridomas and monoclonal antibodies therefrom having specific reactivity toward heavy chain immunoglobulin from catfish
Case Number: cr 7012 received-fy89-7/15/89
Disposition: filed-fy89-7/27/89 sn 385,752

Patent Cases
Inventor: KOLZ AL
Title: surface mounted assembly for biotelemetry
Case Number: aphis denver wildlife received-fy89-10/28/88
Disposition: none

Patent Cases
Inventor: KUYKENDALL LD, Hunter
Title: enhancement of nitrogen fixation with bradyrhizonbium japonicum mutants
Case Number: mb 7009, received-fy89-3/16/89
Disposition: filed-fy89-3/17/89 sn 325,184

Patent Cases
Inventor: LEE IM, Davis
Title: nucleic acid probes for detection of mycoplasma-like organisms
Case Number: e prepared by cooperator, received-fy89-12/21/88
Disposition: filed-fy89-11/14/88 sn 270,939

Patent Cases
Inventor: LEWIS JA, Lumsden, Papavizas, Hollenbeck, Walter
Title: fungal formulation for biocontrol of soilborne plant pathogens
Case Number: received-fy89-2/10/89 joint ARS Grace, filed by Grace
Disposition: filed-fy89-3/13/89 by Grace sn 322,445

Patent Cases
Inventor: LILLEHOJ HS, Ruff, Sevoian, Keller
Title: avian lymphokines protective against coccidiosis
Case Number: mb 6994 received-fy89-3/14/89 joint
Disposition: filed-fy89-3/15/89

Patent Cases
Inventor: LITZKOW CA, Webb?, Masuda?
Title: apparatus and process for detection of insect infestation in an agricultural commodity
Case Number: PD 87-27 ds received-fy89-6/8/89
Disposition: filed-fy89-4/4/89 sn 332,901

Patent Cases
Inventor: LOUIS GL, Salaun
Title: the srrc staple core/wrap yarn producing apparatus
Case Number: pd 87-20, received-fy89-3/15/89
Disposition: dropped-fy89-6/5/89 significant improve. in Sawhney cases

Patent Cases
Inventor: MASON JR, Dolbeer, Preti
Title: mint canine repellent
Case Number: aphis adc, joint Monell, received-fy89-1/31/89
Disposition: filed-fy89-5/12/89, sn 351,841

Patent Cases
Inventor: MAYFIELD JE, Tabatabai
Title: recombinant brucella abortus gene expressing immunogenic protein
Case Number: isurf 945, cip received-fy89-7/24/89 joint IOWA ars
Disposition: filed-fy89-6/12/89 sn 365,226

Patent Cases
Inventor: McELWAIN TF, Hines, McGuire, Palmer, Jasmer, Reduker, Goff, Perryman Davis
Title: novel proteins and cloned genes for diagnosis and prophylaxis of babesiosis
Case Number: w 1046, received-fy89-8/23/89 joint ARS U. of Fla, Wash. State U
Disposition: filed-fy89-4/4/89 by U. of Fla

Patent Cases
Inventor: McGOVERN TP, Williams, Fickle
Title: attractants for the rose chafer, macrodactylus subspinosus (f.)
Case Number: received-fy89-5/30/89 cr 7013 joint ARS Ohio State
Disposition: filed-fy89-5/31/89 sn 359,172

Patent Cases
Inventor: McGUIRE VM
Title: floating water intake
Case Number: SCS received-fy89-5/1/89 rights determination
Disposition: none

Patent Cases
Inventor: McLAUGHLIN RJ, Wilson, Chalutz
Title: inhibiting plant pathogens with an antagonistic microorganism(s)
Case Number: DS 73, 77 b 7043CIP-2, received-fy89-8/23/89
Disposition: filed-fy89-8/18/89 sn 395,681

Patent Cases
Inventor: MICHLER CH, Haissig
Title: methods of high frequency tissue regeneration, regeneration of herbicide-tolerant populus plants therewith, etc.
Case Number: fs 1004 cip of sn 192,408 received-fy89-9/20/89
Disposition: filed-fy90-12/7/89 sn 447,458

Patent Cases
Inventor: MILLS FD, Brown, Mills Jr.
Title: process for the preparation of ketones and novel insecticides produced therefrom
Case Number: 7014 div ds, received-fy89-12/2/88
Disposition: filed-fy89-11/30/88 sn 305,144

Patent Cases
Inventor: MOREAU JP, Bailey, Delucca II
Title: fatty glycolic acid derivatives as yarn lubricants and as antimicrobial agents
Case Number: mb 6987, received-fy89, 10/14/88
Disposition: filed-fy89-10/24/88 sn 261,531

Patent Cases
Inventor: MORRISON JE, Jr.
Title: ground contact implement soil penetration depth control
Case Number: PD 87-25 fwc ds, received-fy89-3/2/89
Disposition: filed-fy89-3/6/89 sn 319,795

Patent Cases
Inventor: NAIR PP, Kessie
Title: novel aminoglycoside affinity media for separation of macromolecules
Case Number: mb 7001 received-fy89-1/25/89 joint U. of Maryland
Disposition: filed-fy89-1/30/89 sn 302,871

Patent Cases
Inventor: OROZCO EM, Chen
Title: transcription terminators for use with strong promoters of bacteriophage RNA polymerases
Case Number: received-fy89-3/22/89 cr 7007
Disposition: filed-fy89-3/22/89 sn 327,065

Patent Cases
Inventor: PAN HP
Title: p-aminopropiophenone (PAPP) as a selective toxicant for predator control
Case Number: aphis denver wildlife "A" received-fy89-1/23/89
Disposition: dropped-fy89-8/28/89 statutory bar

Patent Cases
Inventor: PAN HP
Title: p-aminobutryophenone (PABP) as a coyote control toxic agent
Case Number: received-fy89-1/23/89 aphis denver wildlife "B"
Disposition: dropped-fy89-8/28/89 statutory bar

Patent Cases
Inventor: PAN HP
Title: p-aminovalerophenone (PAVP) as a coyote control toxic agent
Case Number: received-fy89-1/23/89 "C" aphis denver wildlife
Disposition: dropped-fy89-8/28/89 statutory bar

Patent Cases
Inventor: PAN HP
Title: p-hydroxylaminopropiophenone (PHAPP) as a coyote control agent
Case Number: received-fy89-1/23/89 "D" aphis denver wildlife
Disposition: dropped-fy89-8/28/89 statutory bar

Patent Cases
Inventor: PAN HP
Title: aspirin as a booster for warfarin (3-alpha-phenyl-beta-acetylethyl-4-hydroxycoumarin) for control of anticoagulant-resistant rodents
Case Number: received-fy89-1/23/89 "E" aphis denver wildlife
Disposition: none

Patent Cases
Inventor: PAN HP
Title: 4,4'-dipropionylazoxybenzene, a novel liquid crystal and a novel monomer
Case Number: received-fy89-1/23/89 aphis denver wildlife "F"
Disposition: dropped-fy89 not pertaining to agency objectives

Patent Cases
Inventor: PEKAS JC, Schanbacher
Title: immunization against cholecystokinin for increases in growth and efficiency
Case Number: cr 6974, received-fy89-3/2/89
Disposition: filed-fy89-3/7/89 sn 320,127

Patent Cases
Inventor: POWELL RG, Mikolajczak, Zilkowski, Clardy, Mantus
Title: organic nitriles as insect antifeedants
Case Number: 6992 mb joint ARS Cornell, received-fy89-6/22/89
Disposition: filed-fy89-6/27/89 sn 371,879

Patent Cases
Inventor: PUSEY PL
Title: biological control of fruit rot
Case Number: received-fy89-8/10/89 sil fwc of cip of 6948 s
Disposition: filed-fy89-8/11/89

Patent Cases
Inventor: RAINA AK, Jaffe, Kempe
Title: peptides stimulating sex pheromone production and melanization in moths
Case Number: mb 7002 received-fy89-5/17/89 joint U. of Maryland
Disposition: filed-fy89-5/19/89 sn 354,326

Patent Cases
Inventor: ROBEL EJ
Title: composition and method for increasing the hatchability of turkey eggs
Case Number: 7011 cr received-fy89-6/5/89
Disposition: filed-fy89-6/8/89 sn 362,992

Patent Cases
Inventor: SAUNDERS JA, Mathews
Title: plant transformation by gene transfer into pollen
Case Number: cr 7017, received-fy89-5/5/89
Disposition: filed-fy89-5/8/89

Patent Cases
Inventor: SAWHNEY APS,
Title: composite-blend yarns of improved strength and method of producing same
Case Number: ds 16, received-fy89-3/20/89
Disposition: none

Patent Cases
Inventor: SAWHNEY APS, Folk, Robert
Title: new and improved techniques for producing staple-core/cotton wrap yarn
Case Number: ds 59, received-fy89-4/4/89 filed by mhs
Disposition: filed-fy89-6/30/89 sn 373,545

Patent Cases
Inventor: SAWHNEY APS, Folk, Robert
Title: system for producing core/wrap yarn
Case Number: received-fy89 ds 59a filed by mhs
Disposition: filed-fy89-6/15/89 sn 366,702

Patent Cases
Inventor: SAWHNEY APS, Folk, Robert, Kimmel
Title: uniquely structured staple-core/cotton wrap ring-spun yarns and the device and method for producing same
Case Number: ds 21, received-fy89-3/20/89
Disposition: filed-fy90-1/24/90 sn 469,120

Patent Cases
Inventor: SHAPIRO M, Lynn, Dougherty
Title: more virulent biotype isolated from wild-type virus
Case Number: 7016 mb, received-fy89-6/28/89
Disposition: filed-fy89-6/30/89 sn 373,977

Patent Cases
Inventor: SHASHA BS, McGuire
Title: adherent, autoencapsulating spray formulations of biocontrol agents
Case Number: 7022 cr, received-fy89-8/3/89
Disposition: filed-fy89-8/3/89 sn 389,090

Patent Cases
Inventor: SOMERS DA, Parker, Wyse, Gronwald, Gengenbach
Title: herbicide tolerance in maize plants
Case Number: received-fy89-3/14/89 joint ARS U. of Minn.
Disposition: filed-fy89-11/10/88 sn 269,584

Patent Cases
Inventor: SPRINGER EL
Title: bleaching lignocellulosic pulps with light, oxygen, water and semiconductor powders
Case Number: fs 1007, received-fy89-12/1/88 connors
Disposition: filed-fy89-11/29/88 sn 277,621 refiled 12/5/88 sn 280,397

Patent Cases
Inventor: SPRINGER EL, Minor
Title: delignification of lignocellulosic materials with monoperoxysulfuric acids
Case Number: fs 1012 received-fy89-3/10/89 connors
Disposition: filed-fy89-3/30/89

Patent Cases
Inventor: STERN NJ, Meinersmann
Title: campylobacter jejuni colonization factor
Case Number: mb 7014, received-fy89-6/14/89
Disposition: filed-fy89-6/16/89 sn 366,983

Patent Cases
Inventor: TISSERAT B
Title: in vitro production of citrus juice vesicles from pre-existing juice vesicles
Case Number: w 1047 ogc 87-14, received-fy89-5/1/89
Disposition: filed-fy89-8/3/89 sn 389,194

Patent Cases
Inventor: VANDERMEER RK, Lofgren, Williams, Meyers, Lewis
Title: a method for control of insects
Case Number: received-fy89-11/23/88
Disposition: filed-fy89-10/11/88, sn 256,237

Patent Cases
Inventor: VIGO TL, Frost, Bruno, Danna Frost remarried, is now Zimmerman
Title: temperature adaptable textile fibers and method of preparing same
Case Number: div of cip 6956 S, received-fy89-6/14/89
Disposition: filed-fy89-6/27/89 sn 371,779 patented-fy90-3/13/90 4,908,238

Patent Cases
Inventor: WELCH CM, Andrews
Title: catalysts and processes for formaldehyde-free durable press finishing of cotton textiles with polycarboxylic acids
Case Number: div PD 87-36, received-fy89-3/15/89 fado
Disposition: filed-fy89-4/10/89 sn 335,346

Patent Cases
Inventor: WELLS SP
Title: douglas-fir tree "Torquis" variety
plant patent
Case Number: fs 1015 connors received-fy89-4/18/89 plant patent
Disposition: filed-fy89-4/20/89 sn 341,088

Patent Cases
Inventor: WILSON CW
Title: inhibiting plant pathogens with nonantibiotic antagonistic
microorganisms
Case Number: b 7043 cip ds, received-fy89-7/28/89
Disposition: filed-7/31/89

Patent Cases
Inventor: YATSU LY, Calamari, Benerito
Title: stable crystalline cellulose III polymorphs
Case Number: 6963 s div, received-fy89-7/27/89
Disposition: filed-fy89-7/27/89 sn 385,518

Patent Cases
Inventor: ZARLENGA DS, Gamble
Title: trichinella spiralis antigens for use as immunodiagnostic reagents or
vaccines
Case Number: w 1045 received-fy89-6/9/89
Disposition: filed-fy89-6/15/89

Patent Cases
Inventor: ZUERNER RL
Title: diagnostic and epidemiological nucleic acid probe for bovine
leptospirosis
Case Number: received-fy89-3/22/89 cr 7010
Disposition: filed-fy89-3/22/89 sn 327,064

APPROPRIATION HISTORY

Mr. WHITTEN. Please provide the funding level you requested of the Secretary, the level the Secretary requested of OMB and the OMB allowance for fiscal year 1991.

Mr. RAUL. The numbers were the same throughout the budget process. We requested $23,517,000 and 398 staff years of the Secretary. The Secretary approved our entire request and sent it to OMB. OMB then allowed us the original level of $23,517,000 and 398 staff years.

TRAINING BY ATTORNEYS

Mr. WHITTEN. We are aware that the Office of the General Counsel attorneys spend considerable time throughout the year participating in and conducting many training sessions for the agency personnel. Please provide us some specific examples of the types of training that your attorneys conducted during fiscal year 1989.

Mr. RAUL. OGC attorneys provide or participate in a variety of training programs for agency personnel. Our attorneys, working with their client agencies, have participated in agency-conducted training sessions as resource persons who were available to answer questions posed by attendees, as well as serving on panels, and providing direct training in various areas. I will provide some examples for the record.

[The information follows:]

1. During fiscal year 1989, OGC attorneys trained APHIS staff officers in the methods of planning and preparing regulations relating to the use, testing, or licensing of veterinary biologics. With regard to a number of regulatory enforcement programs such as Horse Protection and Animal Welfare, we conducted symposiums for veterinarians, inspectors, compliance officers, and headquarters staff personnel on the interpretation and implementation of the provisions under the relevant statutory and regulatory promulgations. Our attorneys have instructed agency personnel as to agency responsibilities under the Freedom of Information Act and the Privacy Act. In the area of marketing orders and research and promotion programs, we have participated in training programs focusing on the rulemaking requirements under the APA, the requirements of antitrust laws, and compliance and enforcement procedures concerning regulated entities.
2. A number of both Washington and field attorneys conducted training for FmHA personnel on Farmer Program loan servicing.
3. In September 1989, an attorney was a member of a panel at an FmHA National Appeals Staff Training Session concerning the handling of appeals involving farmer program loan appraisals and servicing requests.
4. Attorneys conducted informal training sessions for Rural Electrification Administration employees on the debarment and suspension regulations, the restrictions on lobbying regulations and certification regarding lobbying, the Administrative Procedure Act, and the Freedom of Information Act.
5. OGC Washington office and field office lawyers provided 6 hours of instruction during the NEPA/NFMA Regional Workshops with Forest Supervisors, land management planners and environmental coordinators. The topics included the National Environmental Policy Act, National Forest Service administrative appeals, judicial review of plan and project decisions and fulfillment of Federal environmental laws.
6. OGC attorneys conducted training at Forest Service personnel training sessions regarding mineral management, fire management, and land management and surveying.
7. OGC attorneys delivered a seminar regarding laws and courts in Forest Service decisionmaking as a part of the Forest Service's Management Policy Seminar held for advocacy Forest Service employees.
8. Attorneys provided Freedom of Information Act (FOIA) training to Food and Nutrition Service (FNS) Regional and National Office personnel on July 20, 1989. The training was held at the FNS National Office and was intended to familiarize

FNS personnel with FOIA requirements and procedures as they pertain to the administration of the Food Stamp Quality Control program.

9. A considerable amount of time was spent by our attorneys during FY 1989 in training agency personnel—both new appointees and other USDA officials—in the areas of ethics and conduct. The subjects covered included the Federal conflict of interest laws, USDA regulations regarding employee responsibilities and conduct, and Hatch Act political activity restrictions.

10. An attorney conducted training for Forest Service personnel on Integrating Legal Requirements Into Forest Service Decision Making in North Carolina in June 1989, in Arkansas in July 1989, and in Virginia in September 1989.

11. An attorney conducted training for Forest Service personnel on Federal Manager's Responsibilities/Liabilities Under Federal/State/Local Environmental Laws and Regulations in Florida in July 1989.

12. An attorney conducted training for FmHA personnel relating to contracting matters in January 1989 and May 1989.

13. In December 1988 OGC sponsored an extensive two-day training session for FmHA and ASCS personnel from the 13 northeastern states at Hershey, Pennsylvania. The conference featured OGC attorney presentations in seminars on the following subjects: Federal Employee Tort Liability; the U.C.C. and Secured Transactions; Lender Liability; Business & Industry Issues; Community Facilities Issues; Conversion; Rural Rental Housing Issues; Hearings and Appeals Preparation; and Bankruptcy. Approximately 150 FmHA and ASCS employees from throughout the northeast attended.

14. In April 1989, attorneys conducted a three-day training session concerning various aspects of FmHA Instruction 1951-S for FmHA Farmer Program Chiefs and several Farmer Program Specialists from Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

15. Attorneys conducted training for Forest Service personnel in Vermont, Minnesota, and Missouri, on real property title review and the proper preparation of land acquisition and exchange case submissions.

16. Attorneys made presentations to Forest Service employees concerning their legal responsibilities under the various Mining Law statutes and regulations at the Forest Service National training center at Marana, Arizona.

17. Attorneys participated in several meetings involving lengthy discussions with APHIS personnel to develop and design a new staff officer training program for APHIS regarding rulemaking, the Administrative Procedure Act, the Freedom of Information Act and the Privacy Act, administrative law, environmental law and certain other matters. Six senior attorneys participated in the delivery of the course, which included lectures on selected topics, the drafting and critique of a proposed rule for publication in the *Federal Register*, and a mock trial concerning a challenge to that rule by a person charged with violating the regulation. The program was very well received by participating APHIS personnel, and it is scheduled to be repeated in the near future. We also provided speakers and lecturers for several other APHIS training courses for compliance officers and Foreign Animal Disease Diagnosticians. Further, attorneys from this office also presented two day-long seminars to FSIS officials regarding the elements of strict liability and specific intent under the Federal Meat Inspection Act and the Poultry Products Inspection Act and preparing investigative reports.

Mr. WATKINS. Mr. Raul we appreciate having your testimony and your insight. Thank you very much.

BIOGRAPHICAL DATA ON ALAN CHARLES RAUL

Alan Charles Raul was nominated by President George Bush, and unanimously confirmed by the Senate, as General Counsel of the U.S. Department of Agriculture. He was sworn in by Secretary Clayton Yeutter on May 22, 1989. Prior to this appointment, Mr. Raul served in the Executive Office of the President as General Counsel of the Office of Management and Budget (1988–1989). He was chief legal advisor to three successive OMB Directors—James C. Miller III, Joseph R. Wright, Jr. and Richard G. Darman. Before moving to OMB, Mr. Raul held a Presidential appointment in the White House as Associate Counsel to the President (1986–1988). Mr. Raul was previously an associate in the New York and Washington law offices of Debevoise & Plimpton and a law clerk to Judge Malcolm R. Wilkey on the U.S. Court of Appeals for the District of Columbia Circuit.

Mr. Raul was graduated from Harvard College and Yale Law School. He also received a Master's degree in Public Administration from the John F. Kennedy School of Government at Harvard University. He is a member of the American Society for International Law, the Council on Foreign Relations, the Federalist Society and various bar associations. Mr. Raul is admitted to practice law in New York and the District of Columbia, as well as before the U.S. Supreme Court and other federal courts. He is a native of New York City.

He is married to Mary Tinsley Raul, who also served in the Bush Administration as Assistant U.S. Trade Representative for Congressional Affairs. They live in Washington, D.C.

BIOGRAPHICAL DATA ON JAMES P. PERRY

James P. Perry was appointed in 1988 to the position of Assistant General Counsel for Natural Resources, U.S. Department of Agriculture, with responsibility for Forest Service and Soil Conservation Service program matters. He joined the Office of General Counsel in 1967 and, following a 2-year tour of duty in the U.S. Army, served as a staff attorney until his appointment as a Deputy Assistant General Counsel in the Natural Resources Division in 1980.

Mr. Perry obtained a Bachelor's Degree from The Citadel in 1964. He received an LL.B in 1967 and an LL.M, with a specialty in Natural Resources Law, in 1974, both from the George Washington University. Mr. Perry is admitted to the practice of law in Virginia and the District of Columbia, as well as before the U.S. Supreme Court and other federal courts.

OFFICE OF THE GENERAL COUNSEL

STATEMENT OF ALAN CHARLES RAUL, GENERAL COUNSEL

UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE

HOUSE SUBCOMMITTEE ON RURAL DEVELOPMENT,

AGRICULTURE AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

Mr. Chairman and members of the Subcommittee, I am pleased to appear before you this morning to discuss the Office of the General Counsel's fiscal year 1991 appropriation request.

INTRODUCTION

The Office of the General Counsel (OGC) is the national law office serving the Department of Agriculture. As a free standing USDA agency integrating all the Department's lawyers, OGC is well positioned to provide independent legal advice to our Departmental clients. We provide a full range of legal counsel and services to the Secretary of Agriculture and each of the Department's 38 agencies and offices. Our full staffing levels are approximately 242 attorneys and 145 support staff in the Washington, D.C., headquarters and the 22 field locations that comprise our five regions across the United States. Fifty-three percent of our personnel is in the field.

FY 1991 BUDGET REQUEST

For fiscal year 1991, we are requesting $23.5 million in direct appropriations. Of the almost $2 million increase, $431 thousand will be used for a new program initiative of pre-decisional environmental legal services, $135 thousand to complete our office automation system, $172 thousand to allow for personnel transfers within the office, and $1.3 million -- or 63 percent -- to cover increases in pay rates and other nondiscretionary operating costs.

GENERAL COMMENTS

As you know, the basic question posed in all recent OGC budget testimony has been how to meet the burgeoning increase in demand for services while holding the line on spending. Last year, we stated that over the past ten years the number of legal matters, particularly cases, referred to this office has increased 350 percent while our major resource -- our people -- has increased only 12 percent.

At the end of the 1979 fiscal year, with a 343 staff-year authorization, OGC was responsible for over 10,000 cases of which approximately 8,500 were civil lawsuits. By the end of fiscal year 1988, with a 385 staff-year authorization, the numbers were 45,000 and 38,000, respectively. To demonstrate the growth another way, the average number of cases for which each attorney was responsible grew from 54 to 176 over the same ten-year period.

Today, I can report that we are beginning to make some headway in reducing our civil litigation caseload. The figures for the end of 1989 as compared to 1988 show a slight decrease. We believe this results from several factors, including changes made by the Congress to aid farmers which have reduced the need for litigation, state mediation laws which affected third party litigation against USDA borrowers, successfully filling vacancies and increasing staff year usage. This good news, however, may only be temporary; we anticipate a substantial number of new cases in the Farmers Home Administration farm program loan area.

Given our current responsibilities, our personnel resources are spread very thin. In fact, an informal survey we have conducted shows that USDA has the second lowest ratio of General Counsel staff to total program staff among all cabinet departments -- with only the Department of Veterans Affairs having relatively fewer lawyers. At the same time, USDA's legal work is among the most complex and diverse of any department. Since our on board strength is not quite up to our authorized ceiling, I have initiated an aggressive recruitment program to fill the remaining vacancies as soon as possible this fiscal year.

There are several areas of our current work that I would like to highlight to demonstrate how OGC serves the Department in ways that go well beyond the processing of cases.

As you well know, many of the major provisions of the five-year farm bill enacted in 1985 expire this year. OGC has been involved in development and preparation of the Administration's 1990 farm bill proposals. As farm legislation moves through the Congress this year, we will continue to provide considerable legal advice, legislative drafting and analysis with regard to this legislation.

OGC greatly assisted Department officials in developing the Administration's policy on food safety regulation and legislation concerning pesticides and pesticide residues in food. We participated in drafting proposed legislation that meets the President's Food Safety Plan and will continue to review and comment on other proposed legislation introduced in Congress concerning food safety.

The steadily increasing prominence of agriculture in the international trade of the United States continues to magnify the demand for legal services in this area. OGC has provided legal advice with respect to United States' proposals on agricultural trade in the Uruguay Round of GATT negotiations, and this work is expected to accelerate as the round approaches completion at the end of 1990. We have also been actively involved in a significant number of GATT dispute settlement proceedings involving agricultural commodities and products.

In addition, I have recently obtained authorization from the Department of Justice for our attorneys to represent the Department's interests in a limited number of natural resources appeals each year before the Federal Courts of Appeals. I believe this will enhance the ability of OGC attorneys to bring their client-specific knowledge to bear on these cases at the appellate level, as well as to sharpen our legal analysis of issues that will have a significant impact on our clients.

PRE-DECISIONAL ENVIRONMENTAL LEGAL WORK

Now I would like to turn to the specifics of our budget. I am requesting an increase of $431 thousand, which corresponds to 13 staff years, to enable us to perform substantial pre-decisional environmental legal work for the Forest Service. This is a necessary, new program initiative to support an effective and aggressive approach to environmental legal work.

The Department's management of national forests has been seriously disrupted by adverse judicial decisions, litigation and administrative appeals involving environmental issues. The Forest Service's decisionmaking has been challenged in recent years under numerous statutes enacted in the past two decades to protect environmental quality. The environmental challenges are often based on the agency's allegedly inadequate documentation of its decisions. Litigation losses have resulted in declines in timber sales, and delays or cancellation of development of recreation sites, roads, land exchanges, mining and mineral leasing and other programs.

We believe that the best strategy for the Department is to form national teams to provide significant pre-decisional legal services to the Forest Service, especially on critical policy initiatives and projects. The most valuable contribution that OGC can make to the defensibility of agency action is early involvement in the preparation of environmental and decision documents.

Right now, OGC is for the most part only able to respond to the Forest Service's legal needs in the environmental law and administrative decisionmaking area by providing post-decisional legal services when a dispute arises. This service strategy may be suited for a situation where there are few administrative appeals and a low potential for judicial review, and when a single judicial decision does not have broad program consequences.

However, a largely post-decisional practice is just not effective in the current state of environmental law and jurisprudence. The number of administrative appeals of Forest Service decisions has dramatically escalated in the past five years, from 439 in 1984 to 1,291 in 1989. The far ranging significance of environmental litigation is best illustrated by the broad programmatic injunction issued in the spotted owl case which involved 168 timber sales. Under current statutes, a single case can have devastating program consequences.

This new preventive law strategy to assist the Forest Service cannot be absorbed within existing resources. The existing caseload precludes the attorneys currently assigned to Forest Service work from participating substantially in pre-decisional planning activities. Therefore, we are requesting approval of this modest increase that would permit us to add ten attorneys and three support staff.

OFFICE AUTOMATION

I am very happy to report that the office automation efforts initiated over the past two years have been effective and are beginning to be of great help to us everyday. With the assistance of this Committee and Congress, we have procured and installed a major portion of our integrated office-wide automation system. Although the system is not yet complete, we have begun to realize some considerable benefits, particularly in the areas of document preparation and intra-office communications.

With the increases appropriated in 1989 and 1990, we have purchased 337 personal computer workstations for both legal and support staff, linked our offices with an elementary telecommunications system, and purchased local area networks to allow each of our field offices to operate as an integrated unit. Increased attorney access to computerized legal research tools will be provided as software is developed.

We are beginning the development and design of the final phase of the system -- internal casetracking, work measurement, archival and other recordkeeping capabilities. However we cannot afford to finish this year. Completing this computer enhancement for OGC is not, in my opinion, merely optional or marginal; it is essential for us to get a handle on our job. Right now, we simply have no accurate and readily accessible means of tracking cases and other legal matters pending in the office. Without this ability, thoroughly responsible management of OGC is very difficult. Therefore, we are requesting a net increase of $135 thousand to complete the system in fiscal year 1991. With the $512 thousand equipment budget already in our base, a total of $647 thousand would be available to complete OGC's computer needs.

PERSONNEL TRANSFERS

A small but important increase is $172 thousand for personnel transfers within the office. Our office is located in Washington, D.C., and 22 field locations across the United States. The field offices are small, ranging from three to 29 staff. In the past, we have been generally unable to afford transfers of personnel among our offices. This has resulted in lost opportunities for both the agency and the employees.

With the new regional structure we implemented last year and our efforts to become an integrated national law office, the ability to transfer personnel has become essential to the management of this office. For example, the new heads of our Mountain and Southern Regions were appointed from within OGC, but had to relocate from other offices. This increase will allow us to manage our personnel resources more effectively and provide more diverse work experiences for our staff.

INCREASED OPERATING COSTS

By far, the largest portion of our 1991 budget request is to cover standard increases in day-to-day operating expenses -- the increasing cost of doing business -- over which we have no control. Specifically, these are $1.1 million for pay costs and $202 thousand for inflation. Because our budget consists primarily of funds for personnel compensation, we have no way to absorb inflationary and pay rate increases other than to reduce our staff. Therefore, these funds are essential to our financial situation.

To be more specific, 85% of our budget is for personnel costs, six percent for Departmental assessments, and four percent to operate both the office automation system and the law library. The remainder -- travel, training, promotions and awards -- accounts for only five percent of our budget. Reducing these items would also significantly impair our ability to get our job done in a professional manner, and would seriously affect morale.

CLOSING

The budget request for fiscal year 1991 is a prudent one that will allow us to fund the 1990 level of legal services in 1991, to provide more emphasis to environmental issues, to move toward becoming a more unified, national law office and to better discharge our responsibility as the legal arm of the Department.

I believe the requested increase from last year's budget is consistent with the President's fiscal goal of ensuring budget responsibility and his policy goal of placing an important priority on environmental issues. The higher budget level remains confining for OGC, and we will still be required to continue to manage our resources carefully.

That concludes my statement, Mr. Chairman. We certainly appreciate the support this Committee has given us in the past. I respectfully request that you approve our budget request so that we can meet the challenges of our legally oriented society and maintain the quality and level of legal services to the Department. I will be happy to answer any questions you and the Committee members may have at this time.

OFFICE OF THE GENERAL COUNSEL

Purpose Statement

The Office of the General Counsel, which, prior to 1955, was known as the Office of the Solicitor, was established in 1910 (70 Stat. 742) as the law office of the Department of Agriculture.

The Office provides all essential and necessary legal advice and services for the Department's ongoing programs. The headquarters legal staff is divided into four sections: (1) Regulatory and Marketing; (2) International Affairs, Commodity Programs and Food Assistance Programs; (3) Community Development and Natural Resources; and (4) Legislation, Litigation, Research and Operations.

Geographic Location. The work of this office is carried out in Washington, D.C., and five regions which include 22 locations as follows:

Atlanta, Georgia.
  Hato Rey, Puerto Rico
  Jackson, Mississippi
  Montgomery, Alabama
  Raleigh, North Carolina

Denver, Colorado:
  Albuquerque, New Mexico
  Missoula, Montana
  Ogden, Utah

Harrisburg, Pennsylvania:
  Chicago, Illinois
  Columbus, Ohio
  Milwaukee, Wisconsin
  Richmond, Virginia

Kansas City, Missouri:
  Lincoln, Nebraska
  Little Rock, Arkansas
  Stillwater, Oklahoma
  Temple, Texas

San Francisco, California:
  Juneau, Alaska
  Portland, Oregon

As of September 30, 1989, the office had 366 employees of which 352 were permanent full-time employees and 14 were other employees. There were 159 permanent full-time employees and 6 other employees located in Washington, D.C., and 193 permanent full-time employees and 8 other employees in the field.

OFFICE OF THE GENERAL COUNSEL

Available Funds and Staff-Years

1989 Actual and Estimated, 1990 and 1991

Item	1989 Actual		1990 Estimated		1991 Estimated	
	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years
Office of the General Counsel	$20,836,000	357	$21,525,000	384	$23,517,000	398
Obligations under other USDA appropriations:						
FS-Bernardi Case	42,011	1	145,000	2	145,000	2
FS-Timber Sales	33,344	1	60,000	1	- -	-
Total, Other USDA Appropriations	75,355	2	205,000	3	145,000	2
Total, Office of the General Counsel	20,911,355	359	21,730,000	387	23,662,000	400

Full-time Equivalent Staff-Years:	1989 Actual	1990 Estimated	1991 Estimated
Ceiling	359	387	400
Non-Ceiling	1	3	3
Total	360	390	403

OFFICE OF THE GENERAL COUNSEL

Permanent Positions by Grade and Staff-Year Summary
1989 and Estimated 1990 and 1991

Grade	1989			1990			1991		
	Headquarters	Field	Total	Headquarters	Field	Total	Headquarters	Field	Total
Executive Level IV	1	--	1	1	--	1	1	--	1
ES-6	1	--	1	1	--	1	1	--	1
ES-5	3	--	3	3	--	3	3	--	3
ES-4	5	1	6	5	1	6	5	1	6
ES-3	3	--	3	3	--	3	3	--	3
ES-2	2	1	3	2	1	3	2	1	3
ES-1	--	3	3	--	3	3	--	3	3
GS/GM-15	20	8	28	20	8	28	20	8	28
GS/GM-14	45	62	107	45	63	108	45	63	108
GS-13	27	16	43	27	16	43	27	16	43
GS-12	21	12	33	21	12	33	21	15	36
GS-11	12	8	20	12	8	20	13	14	27
GS- 9	2	4	6	2	4	6	2	4	6
GS- 8	6	7	13	6	7	13	6	7	13
GS- 7	16	17	33	16	17	33	16	17	33
GS- 6	7	19	26	7	19	26	7	19	26
GS- 5	7	30	37	7	30	37	8	32	40
GS- 4	3	14	17	3	14	17	3	14	17
GS- 3	--	1	1	--	1	1	--	1	1
GS- 2	1	1	2	1	1	2	1	1	2
Total Permanent Positions	182	204	386	182	205	387	184	216	400
Staff-Years									
Ceiling	162	197	359	182	205	387	184	216	400
Non-Ceiling	--	1	1	1	2	3	1	2	3
TOTAL	162	198	360	183	207	390	185	218	403

OFFICE OF THE GENERAL COUNSEL

CLASSIFICATION BY OBJECTS

1989 and Estimated 1990 and 1991

	1989	1990	1991
Personnel Compensation:			
Headquarters	$7,595,217	$8,215,000	$8,916,000
Field	7,293,411	7,704,000	8,262,000
11 Total Personnel Compensation	14,888,628	15,919,000	17,178,000
12 Personnel Benefits	2,527,009	2,619,000	2,864,000
13 Benefits for former personnel	10,800	11,000	11,000
Total Pers. Comp. & Benefits	17,426,437	18,549,000	20,053,000
Other Objects:			
21 Travel	266,604	354,000	511,000
22 Transportation of things	23,034	15,000	40,000
23.2 Communications, utilities and other rent	924,230	911,000	1,117,000
24 Printing and reproduction	32,880	22,000	22,000
25 Other services	519,353	472,000	499,000
26 Supplies and materials	517,766	567,000	638,000
31 Equipment	1,100,250	635,000	637,000
43 Interest Penalty	350	- -	- -
Total Other Objects	3,384,467	2,976,000	3,464,000
Total Direct Obligations	20,810,904	21,525,000	23,517,000
Position Data:			
Average Salary, ES positions	$74,795	$77,505	$93,763
Average Salary, GM/GS positions	$38,947	$40,128	$41,107
Average Grade, GM/GS positions	10.65	10.66	10.63

OFFICE OF THE GENERAL COUNSEL

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in bracket):

Office of the General Counsel:

For necessary expenses of the Office of the General Counsel, [$21,828,000] $23,517,000.

OFFICE OF THE GENERAL COUNSEL

Appropriation Act, 1990		$21,828,000
Budget Estimate, 1991		23,517,000
Increase in Appropriation		+1,689,000
Adjustments in 1990		
Appropriation Act, 1990	$21,828,000	
Gramm-Rudman-Hollings Reduction(P.L. 99-177)	-303,000	
Adjusted base for 1990		21,525,000
Budget estimate, 1991		23,517,000
Increase over adjusted 1990		+1,992,000

SUMMARY OF INCREASES AND DECREASES
(on basis of adjusted appropriation)

Item of Change	1990 Estimated	Pay Cost	Program Change	1991 Estimated
Legal Services	$21,525,000	$1,052,000	+$940,000	$23,517,000

PROJECT STATEMENT
(on basis of adjusted appropriation)

Project	1989 Actual		1990 Estimated		Increase	1991 Estimated	
	Amount	Staff Years	Amount	Staff Years		Amount	Staff Years
Legal Services	$20,810,904	357	$21,525,000	384	+$1,992,000	$23,517,000	398
Unobligated balance	25,096	- -	- -	- -	- -	- -	- -
Total available or estimate	20,836,000	357	21,525,000	384	+1,992,000	23,517,000	398
Gramm-Rudman-Hollings Reduction, P.L. 99-177	--	--	303,000				
Total, Appropriation	20,836,000	357	21,828,000				

EXPLANATION OF PROGRAM

The General Counsel is the chief law officer of the Department and is responsible for providing legal services for all programs, operations, and activities of the Department. The General Counsel is assisted by a Deputy General Counsel and four Associate General Counsels, each of whom is responsible for a portion of the legal work of the Department. The functions of this Office are performed in the Washington office and in five regions which include 22 locations. The Law Library was transferred from the National Agricultural Library in 1982.

The regional offices handle legal work relating to the activities of the Agricultural Stabilization and Conservation Service, Agricultural Marketing Service, Commodity Credit Corporation, Farmers Home Administration, Federal Crop Insurance Corporation, Forest Service, Soil Conservation Service, and the Food and Nutrition Service. By delegation of the General Counsel, legal work relating to other programs and activities of the Department may be handled by a field office.

Legal Advice. The Office of the General Counsel issues both formal and informal opinions on legal questions arising in the administration of the Department's programs; prepares or reviews administrative rules and regulations applicable to the public; drafts proposed legislation; prepares or interprets contracts, mortgages, leases, deeds, and similar documents; prepares patent applications arising out of inventions by Department employees; and considers and determines claims by and against the United States arising out of the Department's activities.

Administrative Proceedings. The Department is represented by the General Counsel in administrative proceedings for the promulgation of rules having the force and effect of law and in quasi-judicial hearings held in connection with the administration of various USDA programs.

Civil Litigation. Civil litigation arising out of the Department's work is handled by the Department of Justice, with the Office of the General Counsel assisting in the preparation and trial of such cases. The General Counsel represents the Secretary in administrative proceedings before the Interstate Commerce Commission involving freight rates on farm commodities and in appeals from the decisions of the Commission to the courts. By delegation, the Associate General Counsel for Legislation, Litigation, Research and Operations represents the Department in certain classes of cases before the United States Courts of Appeals.

Criminal Litigation. Criminal cases are reviewed for the purpose of referring them to the Department of Justice.

JUSTIFICATION OF INCREASES

(1) An increase of $1,992,000 for the Office of General Counsel consisting of:

(a) A net increase of $135,000 for office automation.

Need for Change. With the help of the Congress, the Office of the General Counsel has begun to procure and install an integrated office automation system. Our plan, incorporated into the fiscal years 1989 and 1990 and 1991 budget requests, is to acquire a system of IBM compatible personal computers available to each employee in Washington and in the twenty-two field offices. These personal computers will be linked together in Washington through the Department's existing local area network and through local area networks installed in each field office. The system will also consist of a central storage facility accessible by all employees containing office-wide records and an archive of significant documents.

The system, when finished, will provide faster word processing, electronic sharing of documents, recordkeeping, increased access to computerized legal research, and telecommunications among our 23 offices and between our offices and our client agencies and outside agencies such as the Department of Justice. With these productivity and quality of work will increase within our authorized staffing level.

Nature of Change. With the fiscal years 1989 and 1990 appropriation increases, OGC has acquired and installed a portion of the office automation system. The budget as presented provides sufficient funds to complete the system in fiscal year 1991. With the one-time cost of $512,000 available from FY 1990, $647,000 will be available to complete the telecommunications and data base management capabilities of the system and to provide expanded access to computerized legal research.

(b) An increase of $431,000 for pre-decisional environmental legal work.

Need for Change. This increase would fund pre-decisional environmental legal services and provide a new approach to environmental legal work for the Forest Service. The additional staff -- ten attorneys and three support -- would be located in headquarters and the field.

During the late 1960's and 1970's, Congress enacted numerous environmental laws -- the National Environmental Policy Act (NEPA), the Clean Water Act, Clean Air Act, Endangered Species Act, Historic Preservation laws, Federal Land Policy and Management Act, National Forest Management Act, to name a few. This multitude of statutory enactments has been used by appellants and plaintiffs to raise numerous legal issues and to challenge Departmental decisions, particularly Forest Service land management decisions. In recent years, Forest Service decisionmaking involving timber management and road building, oil and gas leasing, recreational special use authorizations, right-of-way issuance and administration, hard rock mineral development and administration, and land exchanges have all been challenged in administrative proceedings and appeals and federal courts as violative of NEPA and other environmental laws.

Individuals and groups frequently confront Forest Service field level officers (District Rangers and Forest Supervisors) with legal arguments when attempting to influence their decisionmaking. These individuals or groups often obtain legal counsel to argue their positions to such Forest Service officers. Often the groups are part of, or in touch with, national organizations with well-coordinated strategies. Many Forest Supervisors feel that they cannot contend with these organized efforts without having legal review and advise before they make decisions.

OGC has primarily been able to respond to the Forest Service's legal needs in the environmental law and administrative decisionmaking area only by providing post-decisional legal services. In this type of legal service, the focus is on legal advice obtained after a decision has been disputed. This service strategy may be suited for a situation where there are few administrative appeals and a low potential for judicial review, and when a single judicial decision does not have broad program consequences.

One consequence of laws of the type identified above is that a post-decisional practice is not effective. The number of administrative appeals of Forest Service decisions has dramatically escalated in the past five years, from 439 in 1984 to 1,609 in 1988. The number of lawsuits has also increased. The true significance of this litigation is best illustrated by the broad programmatic injunction issued in the spotted owl case which involved 168 timber sales. Under current statutes, a single case can have devastating program consequences.

Through pre-decisional legal advice, the Department and Forest Service would be in a better position to help shape future judicial interpretation of environmental law and decisionmaking procedures. Although some of these environmental laws were enacted over ten years ago, there remain many unsettled issues as to their interpretation.

Nature of Change. This increased budget request would allocate additional legal resources to provide pre-decisional advice and review needed by the Forest Service. The additional legal resources would be used to reinforce the limited number of attorneys now available to review and advise the Forest Service regarding compliance with an increasing range of environmental laws such as those identified above and related administrative practices and documentation. This would enable OGC to help the Forest Service develop critical procedures for various kinds of projects, including the design and preparation of Environmental Impact Statements and Environmental Analyses, consider legal positions on emerging issues, and otherwise assist Forest Service decisionmakers.

It is not feasible to have an attorney located in each of the 123 Forest Supervisors' offices as has been requested. While this request attempts to deal with the problem of rendering further service through a coordinated delivery system, we would divide new legal staff made available for this area of work between field and Washington office locations, with the bulk being assigned to field offices. We are also requesting support staff and funds for travel. Regardless of location of these new positions, we anticipate using them to deliver legal services which would be coordinated by the Washington office to assure consistency and efficient use of these resources. We would anticipate a high level of coordination, communication and support so that legal research, documentation techniques, responses to emerging issues and new strategies are available to the entire network of OGC attorneys who provide legal services to affected clients.

The additional attorneys requested would also be used to assist the Forest Service in writing regulations, manuals and handbooks to improve Forest Service decisionmaking procedures. This is an ongoing task as the Congress, courts and other federal agencies with jurisdiction are constantly adjusting and interpreting these legal authorities. Additional resources would also be provided to coordinate water law matters in the west.

(c) An increase of $172,000 for change of duty station.

Need for Change. OGC is located in Washington, D.C. and 22 field offices. The field offices are small, ranging from three to twenty-nine staff. With the increase of allowable reimbursable expenses associated with change of duty station, this office has been generally unable to afford transfers of personnel among our offices. This has resulted in lost opportunities for both the agency and the employees.

Nature of Change. The proposed increase will fund three changes of duty station. This will allow us to manage our personnel resources more effectively and to provide promotion potential and cross training for our staff.

(d) An increase of $202,000 for operating cost increases.

Need for Change. This increase will provide fiscal year 1990 level of legal services in fiscal year 1991 and will allow the office to fund fully our authorized staff year ceiling.

Nature of Change. Inflation was calculated at the rate of 3.3 percent for all items except library books and Departmental assessments. The inflation rate for books is higher than other items and was estimated at 15 percent. The increase for Departmental assessments was based on cost estimates received from Departmental Administration.

(e) An increase of $650,000 for the 1989 pay raise and $402,000 which represents 50% of the 1991 pay raise. The remaining 50% of the 1991 pay raise and the total 1990 pay raise are being absorbed.

Office of the General Counsel
GEOGRAPHIC BREAKDOWN OF OBLIGATIONS AND STAFF-YEARS
1989 and Estimated 1990 and 1991

	1989		1990		1991	
	Amount	Staff Years	Amount	Staff Years	Amount	Staff Years
Alabama................	$ 178,160	4	$ 180,000	4	$ 190,000	4
Alaska.................	146,193	3	148,000	3	156,000	3
Arkansas...............	582,204	13	588,000	13	622,000	13
California.............	842,308	17	850,000	19	1,043,000	23
Colorado...............	646,008	14	652,000	15	796,000	18
District of Columbia...	11,829,890	162	12,456,000	181	13,598,000	186
Georgia................	1,211,897	28	1,224,000	29	1,333,000	30
Illinois...............	453,697	10	458,000	10	484,000	10
Kansas	752,208	15	760,000	15	804,000	15
Mississippi............	147,243	4	149,000	4	158,000	4
Montana................	438,854	9	443,000	8	469,000	8
Nebraska...............	149,190	4	151,000	4	160,000	4
New Mexico.............	241,950	5	244,000	5	258,000	5
North Carolina.........	129,296	3	130,000	4	138,000	4
Ohio...................	160,339	4	162,000	4	171,000	4
Oklahoma...............	207,797	5	210,000	5	222,000	5
Oregon.................	569,813	12	575,000	13	608,000	13
Pennsylvania...........	603,936	13	610,000	14	645,000	14
Puerto Rico............	181,619	4	183,000	4	194,000	4
Texas..................	508,739	12	514,000	12	544,000	12
Utah...................	283,382	5	286,000	5	302,000	5
Virginia...............	120,575	4	122,000	4	129,000	4
Wisconsin..............	425,606	7	430,000	9	493,000	10
Total, Available or Estimate...........	20,810,904	357	21,525,000	384	23,517,000	398

OFFICE OF THE GENERAL COUNSEL

STATUS OF PROGRAM

The Office of the General Counsel (OGC) serves as the legal advisor and counsel for the Secretary and the program agencies of the Department.

Current Activities: The Office provides legal services for all agencies of the Department. These services include, but are not limited to the following:

-- rendering opinions on legal questions;

-- preparing or reviewing rules and regulations;

-- preparing or interpreting contracts, mortgages, leases, deeds, and other documents;

-- preparing briefs and representing the Department in judicial proceedings and litigation;

-- representing departmental agencies in nonlitigation debt collection programs;

-- processing applications for patents for inventions by the Department's employees;

-- representing departmental agencies in state water rights adjudications;

-- considering and determining claims by and against the United States arising out of the Department's activities;

-- representing the Department in formal administrative proceedings;

-- assisting the Department of Justice (DOJ) in the preparation and trial of cases involving the Department; and

-- representing the Secretary of Agriculture and the Commodity Credit Corporation before the Interstate Commerce Commission, the Federal Maritime Commission, and the International Trade Commission.

Highlights of OGC's fiscal year 1989 operations are described below:

Selected Examples of Recent Progress:

REGULATORY AND MARKETING

Meat and Poultry Products Inspection Acts: Approximately 249 criminal cases, civil injunction cases, civil seizure cases and claims collection cases were referred to the DOJ or otherwise handled or disposed of with numerous successful criminal prosecutions. In addition, 25 administrative proceedings involving the withdrawal of Federal meat and poultry inspection were litigated, including actions against Lincoln Meat Packers, Windy City Meat and Superior Abattoir which resulted in separate trials before different Administrative Law Judges. OGC assisted in defending the Secretary and other officials of the Department in 10 civil court actions, including participating in separate oral arguments involving Great American Veal and Marshall Chernin in Federal district courts. OGC also reviewed, revised, drafted, and cleared approximately 67 notices of proposed rulemaking or final rulemaking dockets, and drafted or reviewed numerous bills and reports concerning amendments to the Acts. OGC also substantially assisted in developing the administration's policy on food safety regulation and legislation concerning pesticides and pesticide residues in food.

Animal and Plant Quarantine and related laws and Animal Damage Control: OGC reviewed, revised, or drafted and cleared 225 proposed regulations, final regulations, and legal notices. OGC also assisted in handling 15 civil court actions which included defending the Secretary and other officials of the Department. OGC has continued to handle a substantial number of administrative cases under the animal and plant quarantine and related laws. OGC attorneys handled approximately 426 such cases during fiscal year 1989. Most of these cases sought the assessment of civil penalties, and OGC obtained 102 decisions in such cases, assessing over $129,000 in civil penalties. In addition, about 100 criminal cases and claims collection cases were referred to the DOJ or otherwise handled or disposed of during the fiscal year. OGC also performed substantial legal services with respect to matters related to the regulation of genetically engineered plants and organisms. OGC reviewed, redrafted and cleared several cooperative agreements, drafted or reviewed legislation and legislative reports and rendered legal advice concerning numerous issues, including Salmonella enteritidis in eggs and the Department's authority to take action under the animal quarantine and related laws. OGC attorneys also participated in and conducted many training sessions for APHIS personnel.

Marketing Agreements and Orders: OGC attorneys devoted substantial legal resources to the milk and fruit and vegetable marketing agreement and order programs. There are 42 milk orders and 44 fruit and vegetable orders in effect. OGC attorneys reviewed and approved over 300 rulemaking dockets, as well as many other documents relating to these orders. OGC also provided daily legal advice to client agencies in connection with a wide variety of matters arising under the marketing order programs. OGC participates in all formal rulemaking proceedings as Department counsel. The fruit and vegetable marketing order program was particularly active. New marketing order programs were implemented for Vidalia onions grown in Georgia and for High Plains potatoes. OGC attorneys provided legal assistance in connection with amendments to the Florida Citrus, Georgia peach, California raisin and Colorado peach marketing orders and the proposed marketing order for European Seedless Cucumbers. Under the dairy marketing order program, OGC provided assistance concerning a proposed new milk marketing order for North and South Carolina, order amendments in Iowa involving a change in the milk marketing area, changes in the procedure of announcing Class II milk prices under federal milk marketing orders, amendments updating the payment provisions of the New York/New Jersey order, and a number of other amendments.

Substantial legal resources were also devoted to the criminal, civil and administrative actions arising under the marketing order programs. These actions included civil forfeitures, injunctive actions, Bankruptcy matters, and challenges to the legality of a variety of marketing order provisions. Some significant federal court cases included challenges to the Department's notice of hearing in an administrative rulemaking proceeding concerning milk marketing orders in the northeast, challenges to the market wide service payments in the Michigan milk marketing order, numerous false claims cases concerning California Navel Oranges, challenges to amendments to the Southern Michigan Milk order, and the review of the Judicial Officer's decision on the 1979-84 navel orange volume regulations. OGC also provided legal services to client agencies in administrative cases involving challenges to the California citrus and the nectarine, peach and plum marketing orders, the California almond advertising program, the Far West spearmint oil marketing order, Class I price adjustments in several Midwest milk marketing orders, and the pooling requirements of the New York/New Jersey milk order.

Agricultural Marketing Act of 1946: OGC provided legal services concerning numerous program matters involving various agricultural commodities under programs for processed and fresh fruits and vegetables, eggs, cotton, dairy products and livestock. OGC attorneys reviewed AMS rulemaking dockets involving revised regulations and upgraded and new standards for the various agricultural commodities. These dockets involved such diverse subject matters as inspection fees for processed fruits and vegetables, cotton, dairy products, and egg products; revisions of the official standards for slaughter cattle, snap beans, pineapples, canned tomatoes, pickles, Christmas trees and sweet peppers; and proposed new standards for papayas and shelled pistachio nuts. In addition, OGC attorneys reviewed rulemaking dockets for FGIS concerning rice and dry peas. Legal advice was provided in connection with numerous questions involved in the administration of the programs under the 1946 Act. OGC provided legal advice and assistance to AMS concerning the Chilean grape tampering incident, including the establishment of document review and certification services in connection with Chilean produce that had been destroyed. In a lawsuit brought against the Department, OGC participated in the successful conclusion of litigation which sought to enjoin the application of shipping point inspection procedures for apples in the State of Washington. In addition, OGC handled several criminal cases and seven formal administrative proceedings seeking withdrawal of Federal meat and poultry grading and inspection services. Additionally, OGC reviewed five notices of proposed rulemaking or final rulemaking dockets.

Research and Promotion Programs: OGC continued to provide a full range of legal services to AMS for existing research and promotion programs authorized under free-standing legislation for cotton, eggs, dairy, potatoes, honey, beef and pork, and for the advertising and promotion program for wool. OGC also provided legal assistance in connection with the implementation of a new research and promotion program for watermelons. OGC reviewed several rulemaking dockets concerning these programs including revisions to the assessment rate for the egg research and promotion program and rulemakings concerning the implementation of the Egg Research and Consumer Information Act Amendments of 1988. Legal assistance was provided in addressing the wide variety of issues presented by these programs. OGC also provided assistance concerning proposed legislation that would authorize new programs for soybeans, limes, pecans, and mushrooms and that would amend the existing potato, honey, egg, and cotton programs. Legal services have continued to be devoted to agency compliance and enforcement under the various programs. Administrative enforcement actions were initiated in several programs, most of which involved failures to pay assessments. OGC continued to assist in the collection of the past due obligations to the Commodity Credit Corporation and Research Board. In addition, OGC referred several enforcement actions to the Department of Justice concerning these obligations. In federal court litigation, the constitutionality of the beef research and promotion program was upheld on appeal in a case involving a challenge to that program.

Animal Welfare Act: OGC spent substantial time and resources assisting APHIS in connection with the Animal Welfare Act program. A significant amount of OGC time was devoted to the drafting and review of the regulations to implement the 1985 Improved Standards for Laboratory Animals Act which amended the Animal Welfare Act. These regulations concern the humane handling, care, treatment, and transportation of animals. Part I, definitions, and Part II, the licensing, registration (including expanded requirements for research facilities) and handling regulations have been implemented. OGC assisted the agency in the review of over 7800 comments from the general public, institutions and other interested persons, and also assisted the agency in connection with proposed Part III of the regulations concerning facilities and transportation standards. Enforcement under the Animal Welfare Act and regulations occupied substantial OGC resources as OGC has continued to advise the agency in response to questions concerning enforcement of the Act and regulations. Several significant cases were successfully concluded. These cases included one which was upheld by the United States Court of Appeals that imposed a twenty-five-year suspension and $45,000 in penalties against an animal dealer. In addition, an administrative action concerning the harassment of APHIS inspectors conducting a compliance inspection of a research facility resulted in a favorable decision by an Administrative Law Judge and is currently on appeal.

Horse Protection Act: OGC spent substantial time and resources providing legal services to APHIS in connection with the Horse Protection Act program. OGC participated in litigation concerning regulations under the Act. It provided assistance to APHIS in drafting regulations in response to one lawsuit and in reviewing the many comments received from the industry, humane groups, and the public. The promulgation of these regulations which concerned the list of devices and equipment prohibited for use on horses at any horse show, exhibition, sale or auction concluded the litigation and spawned a second lawsuit. OGC continues to litigate the second lawsuit and to assist APHIS in developing new regulations concerning the industry self-regulation (DQP) program. OGC also advised APHIS on many aspects of its compliance and enforcement program under the Act and assisted in responding to a variety of inquiries from the industry and the public related to the horse protection program. OGC also instructed APHIS personnel at several APHIS training seminars.

Virus-Serum-Toxin Act: OGC provided substantial legal services concerning the veterinary biologics program. Such services included advice and opinions involving state regulation of biologics, trademarks, patents, labeling, testing, licensing, and other areas involving a number of major drug firms, researchers, state officials, and others. OGC continued to devote a considerable portion of time in providing drafting and review services concerning regulations, testing standards, and guidelines and procedures for implementing USDA's expanded jurisdiction over veterinary biologics. OGC also continued to render assistance in connection with biotechnology and genetic engineering. This included assistance in formulating policies and guidelines, and advice in connection with the testing and licensing of new products.

Grain Standards Act: OGC reviewed and approved over 55 notices and rulemaking dockets issued under the United States Grain Standards Act. The dockets included program matters and issues concerning the wheat and soybean standards, aflatoxin testing of corn, the shiplot inspection plan, establishment of rapeseed standards, equipment calibrations for wheat protein and sunflower seed oil content, and official performance requirements used in testing soybeans for oil and protein content. In addition, OGC has provided legal advice to FGIS in connection with a variety of issues, including grain quality issues, aflatoxin testing, issues concerning the designation of official agencies under the Act to inspect and weigh grain, and matters relating to the administration of the various programs authorized under the Act. OGC continued to work closely with FGIS in connection with its enforcement and compliance program. OGC participated on behalf of FGIS in administrative actions concerning alleged violations of the Act and regulations which were successfully concluded through consent decisions resulting in the imposition of civil penalties in one action and the denial of inspection service in addition to civil penalties in another action.

Transportation: OGC represented the Secretary before the Interstate Commerce Commission in two proceedings involving the availability of covered hopper cars and the sale of railcar availability. OGC also provided legal services to the Department's Office of Transportation on a variety of issues including reports to Congress on transportation issues and comments on rulemaking proceedings before the Department of Transportation and the Federal Maritime Commission involving such issues as the transportation of anhydrous ammonia and the rate provisions for containers in ocean shipping.

Perishable Agricultural Commodities Act: OGC staff rendered 367 opinions concerning contract disputes between members of the perishable agricultural commodities industry. In addition, 41 administrative enforcement actions and 4 "responsibly connected" cases were initiated. There were 43 actions opened on matters involving the trust fund provisions and 14 civil actions were filed in the federal courts. During the fiscal year two administrative enforcement case were brought seeking license revocations against firms for engaging in the commercial bribery of chain store employees.

Packers and Stockyards Act: During fiscal year 1989, 109 disciplinary proceedings, 38 civil actions, 2 criminal actions and 11 reparation cases were initiated. In addition, 124 disciplinary and 16 reparation cases were concluded. Pursuant to section 1324 of the Food Security Act of 1985, OGC reviewed and approved six applications regarding state central filing systems. At the end of the fiscal year, 27 disciplinary actions, 8 civil actions, and 2 criminal actions were under consideration by OGC, and 66 disciplinary and 122 reparation case were docketed and in litigation.

INTERNATIONAL AFFAIRS, COMMODITY PROGRAMS, AND FOOD ASSISTANCE PROGRAMS

Commodity Credit Corporation (CCC) and Agricultural Stabilization and Conservation Service (ASCS): OGC provided significant drafting services and assistance to Department officials during mark-up of legislation, principally the Disaster Assistance Act of 1989, and various proposals with respect to the Fiscal Year 1990 budget reconciliation and appropriation process. OGC has also provided substantial legal assistance in the formulation and drafting of regulations and other documents needed for the implementation of disaster, price support, production stabilization, conservation and other programs authorized by these Acts and by the Food Security Act of 1985, the Agricultural Act of 1949 and the Soil Conservation and Domestic Allotment Act, as well as various warehousing activities involving CCC and ASCS. Substantial assistance was also provided to ASCS concerning the administration of the Conservation Reserve Program. OGC also provided a significant amount of assistance to ASCS on ASCS and CCC settlement procedures and regulations in order to enhance debt collection efforts of the Department.

Commodity warehouse problems continue to require an extensive amount of resources. OGC has been and continues to be involved in shortage and insolvency matters concerning 81 different warehouse companies having storage contracts with CCC and/or licensed under the United States Warehouse Act administered by ASCS. Substantial legal services were also required in connection with the Conservation Reserve Program, payment limitation and disaster program litigation.

The table below summarizes litigation activity involving CCC and ASCS.

	FY 1988	FY 1989
Number of cases referred for litigation.......................	1,446	1,237
Total dollar value of cases in litigation (in millions).....	199.4	162.7
Number of cases pending in litigation, end of year.........	4,237	3,556
Total dollar value of pending litigation (in millions)........	447.5	391.6

Foreign Agricultural Service (FAS): The steadily increasing prominence of agriculture in international trade relations continues to magnify the demand for legal services in this area. OGC has provided legal advice with respect to United States' proposals on agricultural trade in the Uruguay Round of GATT negotiations, and this work is expected to accelerate as the round approaches completion at the end of 1990. Two OGC lawyers have been named members of the U.S. negotiating group on agriculture for the Uruguay Round. OGC is also providing legal advice to FAS in connection with proposals being made in a number of other GATT negotiating groups, including the groups on subsidies and GATT rules and disciplines, because proposed changes in the current GATT rules often have direct implications for trade in agriculture.

In addition, OGC has been actively involved in GATT dispute settlement proceedings concerning challenges, brought by and against the United States, to import barriers on agricultural products. These proceedings have included, on the one hand, the prosecution of complaints brought on behalf of the United States against Canadian import quotas on ice cream and yogurt and the indirect trade barrier posed by the EC's domestic subsidization of oilseeds and other protein crops used by feed manufacturers. On the other hand, these proceedings have included defense of the complaint by Australia against the U.S. "headnote" quota on imports of raw and refined sugar and the complaint by the European Community against U.S. import fees on refined sugar and import quotas on certain sugar-containing products maintained under section 22 of the Agricultural Adjustment Act of 1933, as amended. Since the GATT panel ruling in favor of Australia, OGC has provided legal analysis and advice on options available for replacing the "headnote" quotas on imports of sugar. OGC has also provided legal advice in the context of consultations pursuant to the GATT with respect to the EC's ban on the importation of meat derived from animals treated with growth-promoting hormones and the imposition by Canada of an import quota on broiler hatching eggs and chicks and new labeling requirements for imported pre-packaged produce.

OGC has also been called upon to provide increased support to FAS in connection with the operation and revisions to the GSM export credit guarantee programs. OGC has advised FAS/CCC with respect to revisions of both its substantive program regulations, as well as its regulations governing suspension and debarment proceedings. OGC is advising FAS on how to proceed towards suspension or debarment of program participants in several specific instances, and has provided legal advice to FAS/CCC and the Office of the Inspector General in connection with several investigations of alleged wrongdoing in connection with GSM guaranteed sales.

FAS has called upon OGC to provide legal services in connection with the United States response to the changing situation in Eastern Europe during FY 1989. This legal assistance primarily involved drafting agreements under the American Aid to Poland Act of 1988, the Food for Progress Act, and Section 416(b) of the Agricultural Act of 1949. OGC will be closely involved in implementing these agreements during fiscal year 1990.

OGC also provided substantial assistance to FAS in connection with the Export Enhancement Program (EEP), specifically in connection with the review of administrative determinations pertaining to various disputes between CCC and exporters participating in the program.

OGC is also involved in the initiative to revise current food aid programs through proposed legislative changes to the Agricultural Trade Development and Assistance Act of 1954 ("P.L. 480") and section 416(b) of the Agricultural Act of 1949.

Federal Crop Insurance Corporation (FCIC): The continued expansion of Federal Crop Insurance because of provisions contained in the Disaster Assistance Act of 1988 and the rewriting of FCIC policies in order to obtain uniformity across delivery systems has required extensive legal services. OGC continued to draft and rewrite program regulations and contractual provisions to simplify and strengthen all aspects of the program ranging from producer participation to reinsurance and agency contractual relationships. OGC has been involved in the collection of funds which should not have been disbursed and in the suspension or debarment of agents in those matters where agents have failed to follow administrative requirements. OGC devoted increased efforts to collections, payments, administrative reviews, and claims. At the end of fiscal year 1989, 284 cases involving claims by or against the corporation totaling 97.3 million dollars were pending in litigation. Increasing resources were required to review cases pending against reinsured companies even though FCIC was not named as a party in the litigation.

Food Assistance Programs: During fiscal year 1989, OGC provided substantial legal advice and drafting support concerning the Child Nutrition and WIC Reauthorization Act of 1989, which not only reauthorized the Child Nutrition and WIC Programs, but made significant changes to the way these programs are conducted as well. In addition, OGC has spent considerable time in implementing the regulatory and administrative requirements of the major amendments made to the Food Stamp, National School Lunch, and Child Nutrition Act in fiscal year 1988. In particular, substantial time was devoted to drafting and review of regulations related to amendments made by the Hunger prevention Act of 1988 which restructured the food stamp quality control system and the related administrative review process. Litigation involving the Department with respect to food assistance programs continues to be a significant element of work (116 cases). Among other issues, the litigation challenged Food Stamp Program rules related to the participation of students in the program and the monthly reporting requirements as well as the validity of state quality control sanctions. In addition to dozens of retailer/wholesaler judicial review cases, there were 27 new court challenges during fiscal year 1989 which involved the administration of the domestic food assistance programs.

COMMUNITY DEVELOPMENT AND NATURAL RESOURCES

Farmers Home Administration (FmHA) Programs: For fiscal year 1989, this Division provided legal assistance to FmHA in all its major areas of activity -- Farmer Program Loans, Single- and Multi-Family Housing Loans, Community Loans, and Business and Industry Loans. These major areas of activity include more than 30 statutorily-separate loan and grant programs. OGC's advice concerned proposed legislation, proposed and final regulations, directives interpreting and implementing regulations, litigation, informal advice, and a variety of legal documents. The total number of work items closed during fiscal year 1989 was 4,869. Formally tracked items amount to perhaps 60 percent of total Division workload. Legislative work included advice to the agency, and working with the Congress on Disaster Assistance Act of 1988, Disaster Assistance Act of 1989, amendments to the Consolidated Farm and Rural Development Act, and other legislative items, including congressional correspondence. Regulatory matters included substantial regulatory materials implementing the Agricultural Credit Act of 1987, the two mentioned Disaster Assistance Acts, the guarantee of FmHA loans, administrative offset, salary offset, and IRS offset. In total, the Division reviewed 455 separate regulatory proposals, which produced 385 pages in the Federal Register. The Division handled referrals from the Department of Justice of more than one hundred litigated cases during the year, and also assisted DOJ in defending especially important cases involving class-action claims against the government or requests for injunctions that had a potential nation-wide impact. This activity included work both at the trial court and the appellate levels. Informal legal advice consists of verbal or written advice to the client on all aspects of administrative law and the laws governing lending and government grant-making. Drafting work included drafting numerous loan agreement and security forms, and agreements concerning loan substitutions and other aspects of the administration of the sale by FmHA of over $2 billion in loan assets at the end of fiscal year 1987, as well as agreements relating to a discount purchase program and another asset sale contemplated for this fiscal year. Work on the secondary market included drafting a complex trust agreement and drafting certificates of investors' interest in a pool of loans, certificates of interest in individual loans, and certificates of residual interest to be held by market-makers in secondary sales. At the end of fiscal year 1989, the Division anticipated an increase in its workload for the future as FmHA finalized its processing of over 62,000 delinquent farm loans, which processing will result in legal activity involving the interpretation of the newly-promulgated regulations as well as litigation challenging collection and foreclosure actions by the agency.

Rural Electrification and Telephone Programs: During fiscal year 1989, the Rural Electrification Administration (REA) and the Rural Telephone Bank (RTB) loan programs required substantial legal services. REA made insured loans totaling $836 million to 176 electric borrowers and 61 telephone borrowers and guaranteed loans totaling $39 million dollars. RTB provided loans totaling $177 million to 28 telephone borrowers. Legal services included the preparation of necessary loan contracts, security instruments and related legal documents. REA and RTB revised certain key lending policies in telephone loan programs and OGC developed new forms of loan contracts, mortgages and notes for telephone borrowers. OGC also negotiated and drafted a generic form of lien accommodation for use by supplemental lenders in the telephone program. In recent years, REA and RTB loans have, on average, required more legal services because more transactions involved such non-standard features as lien accommodations for multiple supplemental lenders and mergers, consolidations or other corporate reorganizations by borrowers.

During fiscal year 1989, REA implemented its new Rural Development loan and grant program and approved the program's first five loans. OGC drafted the regulations and legal documents used in the program. OGC also provided considerable services in drafting regulations to implement a $500 million Federal Financing Bank (FFB) prepayment program pursuant to which FFB loans may be refinanced with private sector loans guaranteed by REA.

OGC drafted and reviewed a large number of regulations on all aspects of the telephone program including loan policies and procedures; policies regarding mergers, consolidations and acquisitions; and requirements regarding materials, equipment and construction standards for REA-financed telephone systems. Also, substantial legal advice and assistance was given in connection with an extensive review of financial structure of power supply borrowers, the security for power supply loans, the form of REA wholesale power contracts, and additional measures available to REA to ensure repayment of loans.

Legal services in connection with financially troubled REA borrowers increased substantially during fiscal year 1989. A total of 9 borrowers, with an aggregate debt of approximately $7 billion, sought restructuring of their indebtedness, including two new borrowers with debt totaling over $1 billion. One complex and lengthy workout was completed in a transaction involving the merger of two power supply borrowers together with the restructuring of outstanding debt to the Government. OGC services included negotiations with the borrowers, other creditors, state regulatory bodies and interested parties as well as the drafting of legal documents implementing the workouts.

Litigation involving REA increased. Four borrowers are in bankruptcy. There are a number of suits associated with severe financial problems, including litigation regarding the right of the Federal Government to preempt actions by state regulatory bodies, and the issues on enforceability of wholesale power contracts between power supply borrowers and their members.

During fiscal year 1989, OGC provided legal advice and assistance to the RTB board, including, for example, opinions regarding director election procedures and draft amendments to the bylaws in several technical areas relating to dividends.

Forestry and Other Land Problems: The controversial nature of national forest management during fiscal year 1989 required legal assistance on a wide variety of litigation, legislation, regulations, policies, and administrative appeals. The development and defense of 123 Land and Resource Management Plans (LRMP's) resulted in over 800 administrative appeals and 8 lawsuits on the 97 completed LRMP's. Approximately 200 administrative appeals were on challenges to individual timber sales. Timber sale contract administration continues to present major legal problems involving defaults, debt collection, bankruptcy, theft, bid rigging, collection and enforcement against sureties, debarments and the need for revised contract forms and procedures. Over 100 timber sale contracts are being litigated involving extension policy and the constitutionality of the U.S. Claims Court. Litigation under the Endangered Species Act and other wildlife laws has proliferated as a consequence of national debates on the protection of the spotted owl, the red-cockaded woodpecker, and the grizzly bear, and has substantially delayed or modified significant agency timber programs.

Accomplishments included a major revision streamlining administrative appeal regulations, implementing improved surety collection procedures, drafting a new national bond form, and the successful suspension and debarment of approximately 50 nonresponsible individuals and entities from the purchase of national forest timber. OGC has also assisted the Forest Service in a nationwide training program on the National Environmental Policy Act (NEPA) for Forest Service line managers. Substantial legal advice and litigation support involved mineral and energy resources occurring on National Forest System lands, including advice on new authorities for oil and gas leasing, complex regulations governing surface disturbance resulting from metal mining, and the disposition of mineral and energy resources under four statutory schemes. Litigation concerning the use of herbicides and pesticides to control the southern pine beetle, gypsy moth, and other forest pests and noxious weeds continued. Legal assistance was provided on land purchases amounting to 45,000 acres; 120 land-for-land exchanges, totaling 118,000 acres; 820 boundary adjustments under the Small Tracts Act; 700 rights-of-way acquisitions; 47 donation cases; and 80 title claims. In addition, the Forest Service received substantial legal assistance from OGC in handling water rights litigation, particularly in Colorado, Idaho, Montana, Nevada, and Oregon, where large scale adjudications are proceeding.

Conservation-minded organizations, industry user groups, and individuals frequently litigated Forest Service decisions concerning timber sales, land use permits, recreation uses, wilderness and roadless area preservation, road construction, grazing use, water use, hydropower developments, and mineral development. Many cases involved alleged noncompliance with requirements of NEPA, the National Forest Management Act, the Federal Land Policy and Management Act, the historic preservation laws, Clean Water Act, and the Endangered Species Act. Legal problems also arose in the field of hazardous waste clean up and regulation, including the Alaska oil spill, and Native American treaty rights and religious freedom issues. At any given time, an average of 300 lawsuits involving Forest Service programs and local forest activities were being prosecuted. Some of these may substantially impede the accomplishment of agency multiple-use goals.

Soil Conservation Service (SCS) Programs: OGC provided legal counsel on range management, flood control and water resources projects, reclamation of surface-mined lands, and natural resource protection; advice on the application of state and federal statutes to programs that affect approximately 3,000 soil and water conservation districts; the defense of lawsuits brought by parties challenging agency activities and the prosecution of claims on behalf of the agency. A significant increase in SCS activities related to assisting farmers, ranchers and other private land users to develop and implement conservation practices that meet federal and state requirements under the Clean Water Act. OGC provided increased legal assistance on the conservation title of the Food Security Act of 1985, which assigns specific responsibility to the SCS for compliance by landowners with the conservation reserve, and sodbuster and swampbuster provisions of the law. There was a heavy demand for legal services on compliance questions, additional rulemaking, appeals under the regulations and other nationwide and individual SCS activities under the Food Security Act. This demand is expect to continue and increase as the next major stage of the phase-in of highly erodible land conservation begins on January 1, 1990, with full phase-in to be completed by January 1, 1995.

LEGISLATION, LITIGATION, RESEARCH AND OPERATION

Legislation: In fiscal year 1989, the staff of the Legislative Division coordinated legal review of 400 legislative reports on pending bills and legislation proposed by agencies of the Department. During the same period staff coordinated legal review of the written testimony of 197 Administration witnesses before Committees of the Congress. The Legislative Division drafted, and coordinated within the Department and with the Office of Management and Budget, the testimony of the General Counsel and amendments suggested by the Department to the Senate with respect to the bill S. 712, the Puerto Rico Status Referendum Act. The staff of this Division also prepared or assisted in preparation of drafts of bills or amendments on request for Members of Congress, Congressional committees, and agencies within the Department. Technical assistance was provided to Congressional committees and advice and assistance furnished to USDA legal and policy officials on the drafting, clearance, and presentation to Congress of legislation and ancillary legislative materials and on Congressional procedures.

Litigation: OGC is responsible for the Department's position in cases on appeal. Staff attorneys assigned to the Litigation Division draft and review documents concerning cases in the United States Supreme Court, the United States Courts of Appeals, and State appellate tribunals. These attorneys also brief and argue certain cases in the Federal Circuit Courts. During fiscal year 1989 Litigation Division attorneys were assigned full responsibility for 16 appellate cases, and they obtained favorable results in five of the cases and unfavorable results in one case decided by the Courts of Appeals. The other ten cases are either fully briefed and argued and under submission for decision, calendared for oral argument in the near future or in the process of having draft briefs finalized for filing. These cases involved diverse subjects and complications. For example, Exportal LTDA v. Yeutter, D.C. Cir. No. 89-1068 (appeal filed Feb. 8, 1989), involves an exceptionally important jurisdictional issue surfaced under the Hobbs Act, 28

U.S.C. §2342, and an unusually delicate question regarding the statutory construction of 7 U.S.C. §499f(e) and the interpretation of an agency rule, 7 C.F.R. §47.6(b). We filed a motion to dismiss the case for lack of subject matter jurisdiction; Exportal opposed the motion; and the motion's panel of the District of Columbia Circuit referred the matter to its merits panel for full consideration of the case. Attorneys in the Litigation Division have drafted an extensive 70-page draft brief in the case. In Hickey v. Department of Agriculture, 9th Cir. No. 88-7281 (June 26, 1989), the Ninth Circuit issued a memorandum opinion after the case was fully briefed and orally argued. The Court of Appeals sustained the Judicial Officer's authority to impose a 25-year suspension of a business license and a $40,000.00 civil monetary penalty for violations of the Animal Welfare Act, 7 U.S.C. §§2131-2156, despite the fact that in a somewhat analogous situation in Bosma v. U.S. Dept. of Agric., 754 F.2d 804 (9th Cir. 1984), that Court invalidated a money penalty under the Packers and Stockyards Act, 7 U.S.C. §§181-229. The Eighth Circuit found Western States Cattle v. U.S. Dept. of Agriculture, 800 F.2d 88 (8th Cir. 1989), to be a very difficult Packers and Stockyards Act case. The Circuit Court ultimately overturned the Judicial Officer's 6-month suspension of Western States registration to do business under the Act on the ground that the evidence supporting the sanction was insubstantial, but it upheld the Judicial Officer's affirmative recordkeeping order in the case. We recommended against certiorari and the Solicitor General agreed. In addition to actually litigating several important appellate cases, the Litigation Division attorneys reviewed and made numerous significant contributions to many of the briefs and arguments in other significant appellate cases involving the Department of Agriculture and handled by Justice Department attorneys. In this regard, Wabash Valley Power v. Rural Electrification Administration, 7th Cir. No. 89-2482 (appeal filed July 13, 1989), is particularly noteworthy. Wabash centers on the unusually important question of whether the agency can preempt a state's ratemaking procedures when its extensive loans to a cooperative utility are jeopardized as a consequence of the rates fixed by the state commission.. Litigation Division attorneys made significant contributions to the brief filed by the Justice Department on behalf of the agency. Finally, but certainly of equal importance, OGC's appellate lawyers prepared the Department of Agriculture's recommendations to the Solicitor General on whether to appeal about 55 adverse decision of various trial courts during FY 1989. All told, Litigation Division attorneys were responsible for a total of approximately 145 appellate cases during the past fiscal year.

Research and Operations: During fiscal year 1989, the Washington office received 82 new administrative claims filed under the Federal Tort Claims Act (FTCA) and 173 claims were open at the end of fiscal year 1989. Currently, 270 FTCA cases are in litigation. At the end of fiscal year 1989, there were approximately 79 cases in litigation or administrative proceedings with "civil rights" implications relating to the Department's personnel policy, grant programs, and direct assistance programs. Legal services are also rendered in the areas of employee conduct (including conflict of interest, conduct proscribed by regulations issued pursuant to executive order, and the Procurement Integrity Act of 1989); budget and fiscal matters; property management; advisory committee activities; internal reorganizations of the Department; and similar matters. Continuing efforts were also made to collect more efficiently money owed to the Department.

OGC provided legal advice to all agencies of the Department engaged in the procurement of construction, supplies, and services. This included drafting and reviewing regulations, reviewing solicitation documents, handling mistake-in-bid and protest matters rendering advice on various preaward and performance issues, and providing the assistance necessary for defending or asserting contract claims. During fiscal year 1989, OGC handled 8 protests relating to the acquisition of automated data processing equipment and related services before the Board of Contract Appeals of the General Services Administration. At the end of fiscal year 1989, 11 of the 348 cases pending before the Department's Board of Contract Appeals were the responsibility of staff attorneys assigned to Research and Operations. The remainder were the responsibility of the field offices or other divisions of the Washington office supporting CCC, FS and FmHA program activities. In addition, 5 procurement related cases for which the Washington office has responsibility were in litigation at the end of the fiscal year. Reviews were conducted and recommendations made on 31 Requests for Proposals (RFP) issued by Departmental agencies for contracts with estimated prices exceeding $500,000. These reviews helped contracting officers to comply with procurement laws and contribute to improved procurement procedures in the Department. At the end of fiscal 1989, six Freedom of Information cases were in litigation. In addition, OGC staff reviewed 148 appeals of final denials under the Freedom of Information Act.

Under the direction of OGC, applications for patents were prepared on inventions by USDA employees and contractors with the objective of obtaining patent protection for the Government. Eighty-five new inventions were reported to OGC during fiscal year 1989. Of these, 78 patent applications were prepared and submitted to the U.S. Patent and Trademark Office. There were 207 applications pending before the Patent Office at the end of fiscal year 1989. Thirty-three patents were obtained, seven applications were abandoned, and 12 cases were otherwise closed.

REGIONAL OFFICES

OGC currently has five regional and seventeen branch offices which provide legal services to numerous USDA agencies that include the Agricultural Marketing Service, Agricultural Stabilization and Conservation Service, Farmers Home Administration, Food and Nutrition Service, Forest Service and Soil Conservation Service. OGC's field offices provide advice and other legal services on all matters within the scope of the delegations vesting, in large agency field staffs located throughout the country, extensive power to implement programs at the state and local level. A majority of the Department's litigation is completed at the local level through direct referrals to the United States Attorneys, without involvement of the Washington office. During Fiscal Year 1989, the Department had 51,481 cases in civil litigation. Ninety-six percent were the responsibility of OGC's 22 field offices.

In addition to work on litigation, work during the year included legal assistance on loan making and servicing; real estate transactions; timber sale and procurement contracts; dealing with violations of state and federal laws; interpretations of state laws that affect federal jurisdiction and programs; application of federal regulations; assuring that local policy decisions were within the scope of delegated authorities and consistent with national policies; municipal financing practices required to meet federal laws and regulations; the effect of state laws on federal lands; uses of national forests; pre-litigation work including negotiations and/or settlements that avoid the need to litigate; and the direct handling of 7,151 nonjudicial foreclosure cases.

During the fiscal year, efforts to reduce the backlog resulted in another modest decrease in the backlog of civil litigation cases; however, the continuous flow of new cases being received makes it very difficult to achieve a reduction.

When new statutes are enacted, adding to or revising agency authorities, such as the Federal Onshore Oil and Gas Leasing Reform Act, Direction in Appropriations Bills (sections 316 and 318 of the Interior Appropriations Act this year), Disaster Assistance Act, Fair Housing Amendments Act, and Stewart B. McKinney Homeless Assistance Amendments Act, legal work is increased for several years because of regulatory changes and questions on interpretations of the new law. Some laws, though not altered, inherently invite continuous litigation over a long period of years. These, which include the National Environmental Policy Act, Endangered Species Act, Coastal Zone Management Act, National Forest Management Act, and Agricultural Credit Act of 1987, in addition to recent enactments, substantially increase OGC's workload.

TUESDAY, FEBRUARY 27, 1990.

FARM CREDIT ADMINISTRATION

FARM CREDIT SYSTEM ASSISTANCE BOARD

WITNESSES

HAROLD B. STEELE, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, FARM CREDIT ADMINISTRATION

ERIC P. THOR, PRESIDENT AND CHIEF EXECUTIVE OFFICER, FARM CREDIT SYSTEM ASSISTANCE BOARD

OPENING REMARKS

Mr. WHITTEN. The committee will come to order.

We will call on Mr. Steele, Chairman of the Farm Credit Administration, at this time.

Mr. STEELE. Mr. Chairman, Mrs. Smith, members of the staff, I am Harold B. Steele, Chairman and Chief Executive Officer of the Farm Credit Administration. Marvin R. Duncan, Second Member of the Board, is with me.

I am pleased to appear before you to discuss the role and the responsibility of FCA and the costs associated with the agency's regulatory mission.

Mr. Chairman, if I might have your permission, I would like to ask that my statement in its entirety be placed in the record, and I will highlight the statement for you, if that would be agreeable.

Mr. WHITTEN. That will be done.

Mr. STEELE. Thank you. Even though my looks might belie my years, I have been a farmer for 42 years. I started real young.

ROLE OF THE FARM CREDIT SYSTEM

During those 42 years, I have found, along with my wife, Marjorie, that it was important for us to participate in the Farm Credit System as we knew it in our community.

There were numerous times when we committed ourselves by signature to long term obligations of the Farm Credit System through the Federal Land Bank Association.

We did this because that association had those qualities and characteristics that we, as young farmers, knew were important to us; a very competitive source of credit, the loan officer knew us and understood agriculture, and it had a reputation of reliability of quality.

Through the years that we participated, we found those qualities to be true and very lasting. Then, as I came here to Washington to take up my duties, I found another dimension of the whole Farm Credit structure as I became involved with the Farm Credit Administration and discovered that indeed the Congress created a very vital role for FCA to perform in making certain that the system was a safe and sound credit system for the farmers and ranchers and the cooperatives that serve them.

It's important that the Farm Credit System remain viable. Also, it's important that the Farm Credit Administration create and maintain a protection for Government and for those who invest in the system and who buy Farm Credit Bank securities.

I also discovered that the Farm Credit Administration had maintained a lid of $36 million plus on its budget for the past couple of years, and, in the current year, was still at that level of $36,121,000.

ADMINISTRATIVE CHANGES AT THE FCA

As a farmer, at the beginning of the fiscal year, we adopted a budget, and we looked at our cash flow, and we adhered to the principles of maintaining with the expenditures of that budget.

When I came to the Farm Credit Administration, I discovered that we had to make some adjustments in order to live within the cap that had been established for us.

We had to increase salaries in order to meet our competition and retain the people that we had attracted and trained just three and a half years ago.

Because other regulatory systems had increased their salaries, we had to match them or come close to them in order to retain these important folks that are vital to our organization.

To keep costs at a minimum, we initiated a hiring freeze. We're currently ten percent understaffed. We also reduced travel, we reduced training, we stopped computer purchases, we postponed certain new projects, we cancelled certain subscriptions to professional journals, and other things to stay within the cap and still carry on the vital important role that the Administration is bound to do under law and of necessity.

FISCAL YEAR 1991 BUDGET REQUEST

As we look, then, to the 1991 budget where we've requested an increase, 90 percent of the increase has to do with salaries, related items, and travel.

Eighty-five percent of the current budget has to do with salaries, related items, and travel. Ninety percent of the new expenditures that we propose are in those vital categories. They have to do with people, because FCA is an organization of people.

The 1991 increase would allow us to cover those pay increases, to remove the temporary hiring freeze, and to begin some high priority items and activities that have been postponed, and in certain areas it would require us to maintain fiscal discipline.

There would be several areas of fiscal discipline that we would be maintaining. The first would be the pay. The comparability for other regulators would not be reached, but at least we would close part of the gap.

The second, the ADP system conversion will be delayed again through fiscal discipline. And the third area would be lower priority projects that will continue to be deferred.

In conclusion, a healthy Farm Credit System, which is very vital to the agriculturalists, the farmers and ranchers, and their cooperatives, must be maintained for the farmers, for the Government, and for the taxpayers.

FCA is the insurance policy to these bodies that we do have that vital organization succeed. Thank you very much.

[CLERK'S NOTE.—The prepared statement of Mr. Steele appears on pages 205 through 213. The explanatory notes for the Farm Credit Administration appear on pages 214 through 220.]

MR. THOR'S OPENING REMARKS

Mr. **WHITTEN**. Thank you very much. I think I'll call on Mr. Thor to go ahead and testify, and then we will go ahead with questions.

Mr. **THOR**. Thank you very much, Mr. Chairman. First of all, Mr. Chairman, I'd like to take a moment to stray from my prepared text and, with your permission, express my sincere appreciation to a fellow Nebraskan who has been a leader in agriculture for over 50 years and has been a primary contributor to many of the successes that this body and others have won for the Nation's farmers and ranchers over all America.

Congresswoman Smith, I'd at least like to extend my congratulations and tell you, as a friend with a family from Nebraska that began dirt farming about 95 years ago, we are indeed appreciative of the kind of leadership you've shown, not only in your time before Congress but in your time in the Midwest.

Mr. **WHITTEN**. We concur in your statement. Mrs. Smith's request to retire is still pending. We haven't acted on it yet.

Mr. **THOR**. Well, Mr. Chairman, let me urge you to have her reconsider. With that, I will begin.

Mr. Chairman, distinguished subcommittee members, it is indeed a pleasure to appear before you again to talk about the Assistance Board and the progress we in the Farm Credit institutions have made to improve agricultural credit for the Nation's farmers and ranchers throughout the United States.

AGRICULTURAL CREDIT ACT OF 1987

The financial assistance mechanism of the Agricultural Credit Act of 1987 is working. Just over two years after the passage of the Act, designed to rescue the Farm Credit System from financial disaster, that system is again on its way to becoming a stable, dependable, agricultural lender for rural Americans.

Although they were crippled in the early 1980s, those Farm Credit institutions have received assistance and are today making progress toward long term viability.

Working through the assistance process, which all of you put in place, the System, with the help of the Assistance Board, has improved credit services to over 225,000 farmers and ranchers in 15 states, which produce over one-third of the Nation's agricultural products by volume.

Mr. Chairman, with your permission, I will not read my entire testimony but would like to quickly summarize some of the most salient points.

Mr. **WHITTEN**. We'd be glad to have you do so.

Mr. THOR. As you know, this has been accomplished while the Assistance Board and the Farm Credit System institutions have used under $1 billion, less than one-quarter of the $4 billion that was authorized by Congress.

It is, in our opinion, still too early to determine exactly how much of that authorization will be needed in the future.

However, we are very cognizant about the need to reduce costs, and the Assistance Board has lowered its administrative budget for fiscal year 1991.

As you know, the Assistance Board does not use appropriated funds to support its operations. The Farm Credit System Financial Assistance Corporation issues bonds to fund the financial assistance to System institutions and to fund our administrative expenses.

The interest on these bonds is paid jointly by the System, and the U.S. Treasury, for which you do appropriate funds. Upon maturity, the bond principal, along with all interest initially funded by Treasury, will be repaid by System entities as defined by statute.

To date, the Assistance Board has certified several banks, including the Bank of Louisville, the Bank of Omaha, and the Bank of St. Paul.

During the last year and a half, the Assistance Board has been concentrating its resources on monitoring and analyzing the financial progress of these assisted institutions.

Each month, the Assistance Board reviews these institutions' financial condition and their performance and makes regular visits to meet with each of the district's boards and management, their independent accountants, and the FCA field examiners, who play an important role.

We continue to meet with farmers and ranchers, also, Mr. Chairman, as you have pointed out to us numerous times, to solicit their opinions toward how well the service and structure is working.

These meetings have been vital to our decision making and monitoring processes. Each of these certified institutions, managements and boards have implemented strategies which, over the last couple of years, has resulted in significant progress.

Indeed, as we look at the Farm Credit System, we can say that the progress in each of the certified areas, as well as the areas served by the former Land Bank of Jackson, has been substantial.

As we mentioned last year, we are mindful of the investment community as they watch the Farm Credit System recovery process.

INVESTOR CONFIDENCE

On average, again this year I can report there has been increased investor confidence in the System, which has further narrowed spreads by approximately 10 to 20 basis points from last years.

The system's total debt of approximately $55 billion should benefit from these narrowed spreads, saving the system, the U.S. taxpayers and farmers and ranchers hundreds of millions of dollars over the next few years.

We continue to remain watchful of investor interests in the Farm Credit System securities. Though the majority of financial indicators show improvement in these certified banks, concerns do remain, Mr. Chairman.

Generally, operating expenses are high in relation to loan volume in System institutions. Non-earning assets, while substantially reduced, remain high in comparison with other financial institutions.

Capital levels within the certified institutions are not yet rebuilt to solid levels, although steps are being taken to do so.

Accrual loan volume of certified institutions and the System as a whole continue to fall below projections. In 1985, the total combined accrual loan volume of the three now certified banks was approximately $19 billion.

By the end of 1988, accrual loan volume in these institutions had fallen to under $12 billion. I'm pleased to report that in 1989 there was some recovery, and in those three institutions loan volume is back up to $12 billion.

The rest of the System saw its volume collapse from over $64.7 billion in 1985, and fall to $48 billion in 1988 and has seen some recovery in 1989.

We remain concerned about these issues and have asked the boards, the management, and the shareholders of these institutions to continue to focus on these remaining problems.

As we look at the Farm Credit System in general, there remain problems over which they have no control, including interest rate levels, food safety, global warming, environmental concerns, cash flow to farmers, and other issues which could threaten farmers and the Farm Credit System alike.

Land values, while they have shown some recovery from 1985 and 1986, could fall again. Each certified institution must take whatever steps necessary to avoid possible dangers which these issues may present.

The Assistance Board staff is committed to helping to ensure continual progress. We have a very small staff and a three member Board of Directors.

As set forth in the Act, the Board of Directors remain the Secretary of Agriculture, the Secretary of Treasury, and a producing farmer nominated by the President and confirmed by the Senate.

Each of these individuals is committed to a better rural America. Our current Chairman, Clayton Yeutter, has pointed out numerous times that we need to have further progress in the Farm Credit System.

ASSISTANCE BOARD BUDGET REQUEST

We continue to stress cost reduction to every institution requesting assistance. The Assistance Board is very cognizant, also, of its own internal budget in this process.

With this conservative principle in mind, the Assistance Board will reduce its administrative budget for 1991 to $2.184 million, a one percent decrease from fiscal year 1990.

As I mentioned before, since we do not use appropriated funds to support our operations, we will depend upon the proceeds of FAC bond sales to provide operating funds and the financial assistance required.

With the timely payment of principal and interest guaranteed by the Secretary of Treasury, FAC bonds today enjoy significantly lower rates than non-U.S. Government-backed bonds.

FAC bonds have a 15-year maturity and pay interest semi-annually. Interest payments on the FAC bonds used to fund assistance packages and system borrower stock are made solely from Treasury for the first five years.

After this period, interest payments will be split with the System, and in the last five years, as well as later on, interest will be paid solely by the System.

It's interesting to point out, Mr. Chairman, that each of the institutions that has received assistance has begun to set up a mechanism to show how it will repay this assistance.

I have attached to my testimony a table showing the amount, the uses and the repayment structure of the FAC bonds outstanding today.

SYSTEM PROGRESS

The outlook for 1990, Mr. Chairman, is that the Assistance Board will continue to concentrate on monitoring assisted institutions and improving the agricultural credit situation for the Nation's farmers and ranchers.

The Farm Credit System has made great progress during the past two years, and we commend them for it. We remind everyone, however, that the return to financial viability is not complete and always subject to possible reversal as a result of another drop in land value or severe adverse climatic conditions or interest rate movements.

Much work remains ahead if the System is to remain the provider of competitive agricultural credit for the Nation's farmers and ranchers.

Working closely with the new Chairman of FCA, we have made substantial progress in the last year, and we look forward to responding to any question you or the illustrious members of your committee have. Thank you.

[CLERK'S NOTE.—The prepared statement of Mr. Thor appears on pages 221 through 226. The explanatory notes for the Farm Credit System Assistance Board appear on pages 227 through 230.]

Mr. WHITTEN. Thank you very much. Our committee has wrestled with this problem for many years, and we have some set ideas about it.

Personally, I never could see the wisdom of separating the Farm Credit System from its banking system, the Congress. It is at our insistence that you submit an annual report to us.

From my experience here, I haven't seen the Farm Credit System take interest in helping the farmer. I told the Secretary when he was here that he was handling what was left of agriculture.

In a period of eight years, we have seen over 300,000 farmers go broke and 70 million acres of land lying idle. We are paying folks not to farm in this country which gives our overseas competitors our markets. We have a policy of letting foreign commodities come in to this country unrestricted. As I've pointed out repeatedly, as many as 640 truckloads of farm commodities came across into the U.S. from Mexico at one crossing in one day.

We have stood by and allowed the American farmer to become dependent on a check from the U.S. Treasury instead of using the Commodity Credit Corporation for loans and purchases to enable him to get his income from the user of his product.

Section 32 of the AAA Act was set up by law to support the price with special attention to perishables commodities, and to promote exports, but this has been taken over by consumer programs.

FCA BOARD

I haven't seen anything that the Farm Credit System has done to prevent any of this from happening. As a matter of fact, last year you had only one member on the Board, so you couldn't act at all.

Now there are two members. Is there nobody willing to serve the farmers and the Farm Credit System? Is a name pending at the White House?

Mr. STEELE. Mr. Chairman, I was at the White House just yesterday, and I visited with the responsible people, as I understand it, for surfacing names for the President's consideration. They are working diligently.

Mr. WHITTEN. I understand how involved this all is. I've had a number of calls from various folks recently, as I've told you in private conversation, and we just haven't had the cooperation that's needed at the highest level in many areas.

Two or three years ago, we had a fellow who headed the Farmers Home Administration who said he was employed to collect money from farmers. Farmers Home required that a loan applicant had to show he could repay everything he owed plus what he wanted to borrow in one year. When the farmer lost his farm, Farmers Home wouldn't sell to any of the kinfolks. Congress passed a law that they had to consider the kinfolks, but it took them a year to act.

Farmers Home has also sat on making crop production loans, and over the last few days I've had a number of folks call that have lost their farms to the holder of the first mortgage because they couldn't get enough money to farm.

I don't know whether we need to rewrite the Act or whether you should give some attention to try to help the farmer. We have laws already in existence that, if used as they were intended to be used, might have a chance to work.

I don't know of any position the Farm Credit System has taken with regards to the import situation. We've got an open door policy when it comes to imports. I say this advisedly, but there are a number of high level officials in the Department that don't seem to realize that the limitations foreign countries have regarding our export products are just trumped up to keep us out.

I've mentioned this repeatedly in the course of our hearing process. A few years ago, and I presume it still exists, England wouldn't let us ship cattle to them because of foot and mouth disease. They had it, and we didn't. Now, once you get rid of one obstacle, they trump up another. Every country does this to protect their industry but us.

The question I ask is, is there anything we can do to get you folks in the act? If you're in the credit business then, you should be interested in the folks that need you, to the point of taking a position in Congress on these laws, many of which have been used opposite from what was intended.

Are you called on by the legislative committee to advise them on what's happening to agriculture? Have you got any interest in the situation other than just counting your money and paying salaries? I'm serious.

Mr. STEELE. Mr. Chairman, I think you bring up an exceeding important point.

Mr. WHITTEN. You can see why I thought it unwise to separate you from your banker—the Congress—and, at our insistence, you report to us once a year.

I am candid when I say that some of your predecessors were less than candid with us.

I'm just asking if there is some way that we might cause the Farm Credit System to have an interest in the farmer and agriculture rather than counting your money and reporting.

Mr. STEELE. I would be pleased, sir, to respond in two instances. First——

Mr. WHITTEN. Maybe I'm talking through my hat, but the situation is deadly serious.

Mr. STEELE. Sir, having a source of credit is one thing, but inability to repay the credit is another.

Mr. WHITTEN. That's right, and I'm asking you as a lender if you can help the farmer get to where he can pay his loan back. If a farmer applies for a loan and Farmers Home turns him down, the bank doesn't want him and your system doesn't want him——

Mr. STEELE. As a regulator, sir, there's a limit, as you know, on what I can do.

Mr. WHITTEN. If you let them all go broke, you won't have anything to regulate.

Mr. STEELE. If I'm ever invited to give some testimony, I'd be pleased to.

Mr. WHITTEN. I'm inviting you now, but you're——

Mr. STEELE. I believe that it's important to bring into the picture in America an improved movement of value added agriculture commodities in meat, milk and eggs, the things that the farmers produce from raw material.

Farmers are most proficient in converting corn and soybeans and other raw material into the highest quality of red meat and milk products and poultry products.

I think this would be most, most vital to the growth of American agriculture, and I would encourage that congressional efforts proceed in this area, which will give more of our farmers opportunity then of using the necessary credit to cause the growth of their business and offer an outlet of product at the market place.

Mr. WHITTEN. I don't know that we can change it, but I've mentioned to the Secretary and others we have had here testifying, that as the present situation goes, the Administration can't give you a very sound position economically. Not as long as we have favored nations, or are sending the Secretary abroad to make markets for Poland and other foreign countries. Not at a time when we've got surpluses and we are paying our farmers not to farm when the world is hungry and begging for food and clothing.

I'm just trying to make a point. In the financing world, are you in a position to carry your views to help that which you're operating and which you're supervising?

Mr. **Steele**. Mr. Chairman, there's another area where the Farm Credit System is very vital and is functioning, and that is in supplying certain amounts of credit for the movement of products to the foreign markets.

Mr. **Whitten**. Do you have any influence in the type of policies that the Government uses, which I think have not been used too wisely at various times?

Mr. **Steele**. I would be please to respond.

Mr. **Whitten**. Are you on the consulting board at the White House at the legislative end? We owe $3 trillion, and a big part of it is because we let American agriculture, our biggest industry, go down. There's no question about it.

That's more than any nation in the history of the world ever owed, and we've added two-thirds of it in the last nine years. I'm asking if you are a part of the group that they might consult with to see if we can prevent that?

Mr. **Steele**. Mr. Chairman, as a regulator, I'm really not in a position to have very much influence in that area.

Mr. **Whitten**. It is most disturbing at this time to know we have this debt, and in the press I read almost daily where the President wants to help some other country out before we find out who we can borrow the money from.

REGULATORY ACTIONS

Last year, Mr. Steele, at the time of our hearing, the Farm Credit Administration did not have a quorum for its board. We had received reports that there were a significant number of pending regulations and actions awaiting the appointment of a second person so the Board could have a quorum. Please provide for the record a short statement on all the regulatory actions the Board has taken since your appointment.

Mr. **Steele**. Since my appointment as the Chairman of the Farm Credit Administration last October, the FCA Board has held seven meetings to address regulatory issues facing the Farm Credit System institutions. Regulatory action has been taken on chief executive officer salary requests that could not previously be acted on without a quorum. The FCA has also adopted an advance notice of rulemaking addressing termination of Farm Credit System status, final regulations deleting certain prior approval requirements, and a proposed regulation permitting non-System ownership of a Farm Credit System secondary market pooler. Also, the FCA Board has approved an agreement in prinicple regarding the sale of most of the remaining assets of the FLB/FLBA of Jackson in receivership.

ISSUES FACING THE FARM CREDIT ADMINISTRATION

Mr. WHITTEN. Your budget justification for fiscal year 1991 indicates that an assessment done by the Farm Credit Administration prior to submittal for the 1991 budget determined that there were 27 issues and sub-issues requiring resources beyond those routinely required by examination and enforcement activities, and because of fiscal constraints, you only included the highest priority of those in determining your fiscal year 1991 request. For the record please list the issues and sub-issues that you consider to be of highest priority.

Mr. STEELE. In response to the numerous and significant changes made to the Farm Credit System (FCS) by the Agricultural Credit Act of 1987 (1987 Act), especially by the restructuring and capitalization provisions, the FCA identified 15 major categories of issues that need to be analyzed and addressed, as appropriate, in the discharge of its regulatory responsibilities. These issues are best understood by describing the categories of issues, since the submission may change as some are resolved and new ones emerge. Most of the categories relate to substantive issues of safety and soundness, but a number of them are operational issues that need to be addressed to allow the FCA to respond to the new regulatory challenges effectively and efficiently. I will provide a more detailed description for the record.

[The information follows:]

1. *Bank supervision of associations.*—The emphasis on association autonomy and local control evident in the 1987 Act, particularly in the restructuring and capitalization provisions, the deletion of the FCA's authority to delegate its authorities, and the prohibition on the removal of association management by the bank, requires reevaluation of the appropriate scope of the bank's supervisory authority over associations. This issue arises in a number of contexts in existing regulations.

2. *Capital.*—The significant alteration of the capital provisions of the Act and the statutory protection afforded outstanding borrower stock by the 1987 Act raise issues related to the appropriate treatment of protected stock in various contexts, the characteristics of permanent capital, and the implementation of the risk-based capital standards adopted in response to statutory direction in the 1987 Act. The change in emphasis from capitalizing the loan to capitalizing the institution and the potential for public stock sales has far-reaching implications in many contexts.

3. *Lending regulations.*—This group of issues relates to adjustments to regulations needed to reconcile authorities of institutions of different types that can now be merged, to set forth the lending authorities of the various types of institutions that can now be created under the restructuring provisions of the 1987 Act, and to set meaningful lending limits for each of these institutions. Appraisal regulations also need to be reconsidered in light of recent congressional focus on the importance of adequate and objective appraisals. In addition, a number of issues related to the lending relationship between the bank and the association must also be addressed in regulations in order for the FCA to make the transition from approving financing agreements to a more regulatory posture without compromising safety and soundness or the FCA's ability to provide meaningful oversight of liquidations.

4. *Liquidations and receiverships.*—The stock protection provisions of the 1987 Act have raised issues regarding the allocation of impairments and the effect of these provisions on existing liquidation regulations. Also, the liquidation of the Federal Land Bank of Jackson and a number of associations has raised numerous issues related to liquidation and the administration of receiverships and has created the need to consider issues related to potential liquidations, including the appropriate definition of insolvency, exploring alternatives to receivership in voluntary dissolutions, and strengthening administration of receiverships.

5. *Restructuring.*—The numerous restructuring options provided by the 1987 Act for Farm Credit institutions have created a flood of applications for FCA approval of mergers of unlike institutions, transfers of direct lending authority, district transfers, termination of System status, special reconsiderations for splitting up merged associations, and almost every conceivable combination of the above. The issues gen-

erated by these applications are complex and often complicated by an endless variety and combination of circumstances and by the effects of the implementation of the new capitalization requirements. Among these issues are those arising from the potential for overlapping territories resulting from giving effect to certain restructuring provisions, issues related to the termination of System status, issues arising from the downstreaming of long-term authority and assets from banks to associations, and issues arising from the deletion of the district boards and the emphasis on greater association autonomy, including joint management issues.

6. *Financially related services.*—Initially, it was anticipated that Farm Credit institutions would propose to offer new types of financially related services in an attempt to offset the economic effects of a decline in loan volume and to retain existing borrowers for whom new at-risk stock provisions might provide a disincentive to borrow from FCS institutions. Although few applications have been filed to date for new and different types of services, any applications that may be filed can be expected to present many issues of first impressions and, if they are approved, new regulatory challenges.

7. *Borrower rights.*—These issues are largely interpretive, often relating to the interplay of various statutory provisions and operational issues relating to the role of the agency in the enforcement of borrower rights and in individual borrower complaints. These issues are complicated by the conflict among court decisions regarding whether there is a private right of action and conflicting judicial interpretations of the various statutory provisions.

8. *Funding.*—This group of issues relates to the need to refine the policies, procedures, standards, and/or regulations needed to provide appropriate supervision of asset/liability management, appropriate exercise of the FCA's bond approval authority, and effective oversight of securities issuance generally.

9. *Secondary market.*—The advent of the secondary market for farm real estate and rural housing loans creates new examination and supervisory responsibilities for the FCA. Farmer Mac and the System pooler affiliate will be engaging in new types of activities posing different types of risks from those posed by portfolio lending, which may require new regulatory responses. In addition to its new regulatory responsibility for Farmer Mac and the System pooler, the participation of Farm Credit institutions in the secondary market requires the resolution of numerous regulatory issues relating to the treatment of the subordinated participation interest in a number of contexts, such as capital, lending limits, investment authorities, and the calculation of insurance premiums.

10. *Farm Credit System Insurance Corporation (FCSIC).*—A number of issues are related to the establishment of the financial, legal, and organizational framework of the FCSIC, the appropriate scope of the FCSIC's examination function, and the relationship of the FCSIC to the FCA.

11. *Supervisory approach.*—The FCA recognizes the need to develop a supervisory approach that is more predictive than in the past and that facilitates early issue identification and prompt and effective responses to developing threats to safety and soundness. This is especially important in view of the removal of numerous prior approval requirements by the 1987 Act.

12. *Legislative issues.*—There is a continuing need to track relevant legislative developments and to understand their impact on the Farm Credit System and the role of the agency as its regulator. When these issues arise, the FCA must evaluate whether the proposed legislation provides adequate regulatory tools for effective oversight of the safe and sound operation of FCS institutions. Recent legislative issues requiring FCA attention include FIRREA, rural development legislation, and the 1990 Farm Bill.

13. *Regulation development.*—The number of regulations required by the 1987 Act to be written within a short period of time highlighted the need to develop effective and efficient internal procedures for initiating and processing regulation changes. Task forces were organized as a temporary measure to deal with the large volume of regulations requiring immediate action, but a more permanent solution is needed.

14. *Information management.*—In order to better coordinate the development of agency objectives with budget preparation, and in order to make possible a supervisory approach that emphasizes predictive capability and early response, consideration of the development of a comprehensive management information system was identified as a high priority issue.

15. *Staffing and budgeting issues.*—Staffing needs, staffing allocations, and resource allocations were identified as issues that need to be addressed in light of the structural changes in the System, the change in the supervisory focus made necessary by the deletion of prior approval authorities, and additional regulatory responsibilities imposed by the 1987 Act.

FEDERAL AGRICULTURAL MORTGAGE CORPORATION

Mr. WHITTEN. The Agricultural Credit Act of 1987 created the Federal Agricultural Mortgage Corporation, commonly known as "Farmer Mac." Can you describe for us to what point the Farmer Mac has developed and when it expects to issue its first mortgage-backed securities?

Mr. STEEL. Farmer Mac has issued its stock, written its bylaws, and hired a skeleton staff. Farmer Mac has hired a general counsel, a corporate relations person, a mortgage-backed securities specialist, and an agricultural lending specialist. Farmer Mac has established standards for underwriting, appraisal, pooler certification, and pool diversification. A pooler certification agreement has been developed and a master trustee for Farmer Mac-guaranteed securities selected. In January, Farmer Mac published its Securities Guide for sellers and servicers. Although, to our knowledge, no poolers have been certified, Farmer Mac has said in its public statements that it can act on a pooler certification agreement within 2 weeks of receipt. We have no information regarding when Farmer Mac expects to issue its first guarantee of mortgage-backed securities.

Mr. WHITTEN. When Farmer Mac proposed its underwriting standards, the FCA expressed some concern about these standards. What is the status of Farmer Mac's standards? Have they altered their plan to address your concerns?

Mr. STEEL. As you know, the FCA was directed by the Congress in the legislative history of the 1987 Act not to write Farmer Mac's underwriting standards. However, the FCA has safety and soundness concerns, which were communicated to the Congress in hearings on the standards, with the underwriting and pool diversification standards. Our concern with the underwriting standards is not so much with the standards themselves as with the ability of Farmer Mac's management to waive the standards without any board limitation. Our concern with the pool diversification standards is that they do not go far enough to prevent geographic and commodity concentrations and can also be waived by Farmer Mac's management. Farmer Mac's management has assured us that it will not guarantee pools with a high degree of credit risk or geographic and commodity concentrations. Except for management's assurance that it will not permit excessive geographic and commodity concentrations, Farmer Mac has not responded to our comments. Since the standards do not ensure that these concentrations will not occur, the FCA will need to evaluate Farmer Mac's performance in that regard on a pool-by-pool basis in the course of the examination process.

Mr. WHITTEN. How many resources has FCA, in terms of FTEs and funds, put into monitoring Farmer Mac to date? At what stage will you bill them for your costs?

Mr. STEELE. The Farm Credit Administration maintains time records, by institutions, for its Office of Examination, but does not keep such records for its other administrative functions. From October 1, 1989, through March 2, 1990, the Office of Examination has devoted 315 hours or 0.15 FTEs to monitoring and examining Farmer Mac. This amounts to $9,506 in salaries and benefits. Significant resources were also devoted to Farmer Mac by the Office of General Counsel and the Office of Financial Analysis. These costs are part of a general overhead allocation. Once Farmer Mac is operational, it will be necessary for FCA to examine any Farm Credit loan pooling operation and loan servicing by Farm Credit System loan originators. The amount of resources to be devoted to these activities cannot be readily estimated at this point. The FCA is currently evaluating its formulas for allocating costs among Farm Credit System institutions. Therefore, the timing and method of billing Farmer Mac is uncertain.

Mr. **Whitten**. We understand Farmer Mac has signed an agreement with the Farmers Home Administration to act as a secondary market for FmHA guaranteed loans. Please explain how FmHA government guaranteed loans will be further guaranteed by implied Government backing through Farmer Mac.

Mr. **Steele**. Since we are not a party to the agreement and were not consulted in its development, we are unable to comment on what is contemplated under the agreement. At the request of OMB, we have commented on legislation the Administration is considering recommending in the farm bill to allow Farmer Mac to pool, securitize, and guarantee the guaranteed portion of FmHA loans. I will provide, for the record, a letter to OMB which notes that we are unable to tell from the draft legislation exactly what is contemplated. However, the draft legislation would expand the definition of "certified agricultural mortgage marketing facility" in the 1987 Act to include Farmer Mac with respect to FmHA-guaranteed loans. This would allow Farmer Mac to pool, securitize, and guarantee such loans. The draft legislation would also expand the definition of "qualified loan" in the 1987 Act to include FmHA loans, except that such loans would be exempt from Farmer Mac standards for "qualified loans." This would appear to allow all certified poolers to pool and securitize FmHA loans. We are unclear as to whether this effect was intended. Although this new activity would expose Farmer Mac to liquidity risk to which it is not now subject, we are not in a position to evaluate the magnitude of the risks to Farmer Mac until the program is more fully defined.

[The information follows:]

Farm Credit Administration

1501 Farm Credit Drive
McLean, Virginia 22102-5090
(703) 883-4000

FCA
FARM CREDIT ADMINISTRATION

February 20, 1990

Mr. Ronald K. Peterson
Office of Legislative Reference
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Peterson:

This responds to your letter of February 12, 1990, requesting our comments on the draft statutory language to implement the "Farm Credit" portion of the Department of Agriculture's (USDA's) recommendations for the 1990 Farm Bill. The draft statutory language would amend Title VIII of the Farm Credit Act of 1971 (1971 Act) to permit the Federal Agricultural Mortgage Corporation (Farmer Mac) and "any affiliate thereof" to act as a certified agricultural mortgage marketing facility for any portion of a loan guaranteed by the Secretary of Agriculture pursuant to the provisions of the Consolidated Farm and Rural Development Act, Title III of P.L. 87-98, as amended (FmHA loans). Under the proposal, such activities would be exempt from certain provisions of Title VIII of the 1971 Act, including underwriting standards, pool diversification standards, reserve requirements and subrogation provisions.

Although you indicate that clearance of the conceptual recommendations has been given, we have not previously had an opportunity to comment on either the substance or form of the proposal, inasmuch as your February 12 communication, which we received on February 15, 1990, is the first formal notification we have had of the specific proposal. Therefore, we have not had sufficient time to conduct a thorough analysis of the ramifications of the proposal for the Farmer Mac program. Nor have we had an opportunity to review any feasibility studies USDA may have conducted prior to drafting the proposal. Nevertheless, we think it important to respond to your request for our comments with some preliminary thoughts on the proposal, in view of the significance of the proposed amendment and its implications for Farmer Mac and for the FCA as its primary regulator.

It is unclear to us whether the proposed amendment is merely intended to empower Farmer Mac to act as an approved market maker under Subtitle B of Title VII of the Agricultural Credit Act of 1987 (1987 Act), or whether the proposed amendment is intended to shift the burden of guaranteeing such securities to Farmer Mac. As you know, Subtitle B of Title VII of the 1987 Act authorizes the Secretary of Agriculture to, directly or through an approved market maker, issue pool certificates representing ownership of part or all of the guaranteed portion of FmHA loans and guarantee the timely payment of principal and interest on such securities issued by approved market makers. However, the effect of the amendment is that Farmer Mac would be empowered to pool FmHA loans, issue (directly or through an affiliate) securities backed by them and guarantee such securities.

In either case, the proposed amendment would involve Farmer Mac in pooling and securitizing loans, a completely different type of activity from the guarantee activity currently authorized by Title VIII of the 1971 Act. Although this activity exposes Farmer Mac to new risks, no changes are proposed to the provisions of Title VIII relating to capitalization, reserves, or guarantee fees. Also, no limits on the amount of such securities Farmer Mac could issue and/or guarantee are proposed, and presumably the same line of credit ($1.5 billion) would back Farmer Mac guarantees on both programs.

Although only the guaranteed portions of FmHA loans would be securitized and these would presumably present little credit risk to Farmer Mac, the program would present a significant new liquidity risk to Farmer Mac, as the issuer will have to continue to make principal and interest payments on the securities while collection proceeds and the USDA guarantee is activated. Furthermore, there are no provisions in the proposed amendment regarding the structure of the market, the interface between the USDA guarantee on the loans and the Farmer Mac guarantee, or the subrogation of Farmer Mac to the claims of security holders in the event it has to advance funds. Nor are there any provisions in the proposed amendment relating to the priority of cash flows between the holder of the unguaranteed portion and the guaranteed portion of FmHA loans sold into the secondary market. Because these matters are not addressed at all in the proposed amendment, it is not possible to assess the magnitude of the liquidity risk or identify other risks that may exist. However, it is safe to say that the risks to the safety and soundness of Farmer Mac could be significant, yet no changes are proposed to the provisions of Title VIII of the 1971 Act designed to ensure its safe and sound operation and to reduce the likelihood that the Treasury line of credit will be activated. In particular, the new risks to be undertaken by Farmer Mac in pooling loans and issuing securities underscore the importance of capital to the safety and soundness of Farmer Mac and to protect the assets of the Treasury.

In addition to safety and soundness issues, we are also concerned that adequate consideration be given to the market ramifications of having Farmer Mac simultaneously administer an essentially commercial enterprise and a Government program, both for Farmer Mac guaranteed securities and for FmHA securities. The following points should be considered:

> —Market reception of Farmer Mac securities could be affected by confusion between securities backed by pools of USDA-guaranteed loans issued and/or guaranteed by Farmer Mac and Farmer Mac-guaranteed securities backed by pools of loans that meet Farmer Mac's underwriting standards.

—Since the proposed amendment would expand the definition of qualified loan to include FmHA loans, it appears that certified facilities would also be authorized to pool and securitize such loans, and nothing in the statute as it would be amended would prevent the commingling of FmHA loans with loans meeting Farmer Mac underwriting standards in the same pool. It is unclear what effect this would have on market reception, but it clearly increases the pooler's liquidity risk.

—Legislative and regulatory changes to the FmHA program, especially borrower rights provisions, could create uncertainty in the market and could affect market reception for securities backed by loans that meet Farmer Mac underwriting standards as well as the market for securities backed by FmHA loans.

—The proposed amendment may in fact result in a higher cost of credit to FmHA borrowers than credit delivered under Title VII of the 1987 Act. Under Title VII, the Secretary of Agriculture is not permitted to charge a guarantee fee for guaranteeing the securities of market makers, but Farmer Mac can charge up to 50 basis points as a guarantee fee and will need to be compensated in some manner for pooling and securitizing loans. Also, it would appear that such securities must be registered with the Securities and Exchange Commission.

While we have not had time to analyze the market impact, we recommend, at a minimum, that appropriate measures be taken (including possibly additional statutory provisions) to differentiate the securities for the investing public. Additionally, the authorization of Farmer Mac to pool and securitize loans that are not required to meet Farmer Mac underwriting, pool diversification, appraisal standards and repayment standards would heighten the concern expressed by the FCA during Congressional oversight hearings that the wide discretion allowed to the management of Farmer Mac in administering its standards would permit the quality of the pools to compromised in an effort to create a market for the securities, increasing the risk to Farmer Mac and to the United States Treasury.

Inasmuch as the structure of the program under consideration is not clear from the draft statutory language, it is not possible to evaluate the extent of the potential risks identified or identify all of the risks that the program may present. We strongly urge, however, that the market ramifications, the risks we have identified, and any additional risks that may be apparent from a more detailed description of the program be considered and addressed before the legislation is recommended to Congress.

Lastly, if the legislation is to be recommended by the Administration, we recommend that the authority of the FCA to regulate and examine all of the activities of Farmer Mac and any affiliate it may be authorized to form be clearly stated, and that any ambiguities that may exist because of the authority of the USDA to regulate market makers under Title VII of the 1987 Act be resolved. Also, since the FCA has primary regulatory and examination responsibility for Farmer Mac, the proposed amendment would appear to result in significantly expanded regulatory responsibilities for the FCA, for which existing resources may not be adequate.

We appreciate the opportunity to comment. If we may be of further assistance, please do not hesitate to let us know.

Sincerely,

Harold B Steele by RKH

Harold B. Steele, Chairman
Farm Credit Administration

cc: Clayton K. Yeutter
Secretary of Agriculture

John R. Dahl, Chairman
Federal Agricultural Mortgage Corporation

FARM CREDIT ADMINISTRATION SALARIES AND GEOGRAPHIC DIFFERENTIALS

Mr. WHITTEN. Mr. Steele, in December you announced increases for general salary and geographic differentials. For the record, please list the locations and applicable differentials and an updated general salary schedule.

Mr. STEELE. I will provide a list of the locations and the applicable geographic differentials as well as an FCA 1990 salary schedule for the record.

[The information follows:]

	Percent
Albany, NY	5.1
Bloomington, MN	7.1
McLean, VA	9.6
Sacramento, CA	4.5

FCA PAY SCALE 1990, EFFECTIVE JANUARY 14, 1990

Step grade	1	2	3	4	5	6	7	8	9	10	WGI amounts
VG-1	$10,898	$11,263	$11,625	$11,986	$12,350	$12,563	$13,920	$13,280	$13,297	$13,629	(1)
VG-2	12,254	12,545	12,951	13,297	13,445	13,840	14,236	14,631	15,027	15,422	(1)
VG-3	13,371	13,817	14,263	14,709	15,155	15,601	16,047	16,493	16,939	17,385	$446
VG-4	15,010	15,511	16,012	16,513	17,014	17,515	18,016	18,517	19,018	19,519	501
VG-5	16,794	17,354	17,914	18,474	19,034	19,594	20,154	20,714	21,274	21,834	560
VG-6	18,719	19,343	19,967	20,591	21,215	21,839	22,463	23,087	23,711	24,335	624
VG-7	20,801	21,494	22,187	22,880	23,573	24,266	24,959	25,652	26,345	27,038	693
VG-8	23,038	23,806	24,574	25,342	26,110	26,878	27,646	28,414	29,182	29,950	768
VG-9	25,446	26,295	27,144	27,993	28,842	29,691	30,540	31,389	32,238	33,087	849
VG-10	28,022	28,956	29,890	30,824	31,758	32,692	33,626	34,560	35,494	36,428	934
VG-11	30,788	31,814	32,840	33,866	34,892	35,918	36,944	37,970	38,996	40,022	1,026
VG-12	36,900	38,130	39,360	40,590	41,820	43,050	44,280	45,510	46,740	47,970	1,230
VG-13	43,879	45,342	46,805	48,268	49,731	51,194	52,657	54,210	55,583	57,046	1,463
VG-14	51,852	53,580	55,308	57,036	58,764	60,492	62,220	63,948	65,676	67,404	1,728
VG-15	60,992	63,025	65,058	67,091	69,124	71,157	73,190	75,223	77,256	79,289	2,033
VG-16	71,535	73,919	76,303	78,688	80,536	81,821	84,159	86,497	88,034		(1)
VG-17	82,155	84,893	87,630	88,034	88,065						(1)
VG-18	89,282										

[1] Varied.

FEDERAL AGRICULTURAL MORTGAGE CORPORATION

Mr. WHITTEN. While it may be too early to determine yet, do you as Chairman of the Farm Credit Administration have a feeling for how Farmer Mac will impact the Farm Credit System entities? Do you believe competition from Farmer Mac will severely limit the Farm Credit System institutions' ability to compete in the lending markets?

Mr. STEELE. Farmer Mac's effect on Farm Credit institutions depends both on market conditions and the response of Farm Credit managers to the Farmer Mac market. However, we expect the Farm Credit institutions to be competitive with the secondary market and other originators and poolers through their existing lending programs. Their large volume in agricultural and rural housing originations makes them a factor in both kinds of lending. When viewed in this light, the ability of Farm Credit institutions to compete should not be severely constrained by Farmer Mac.

While Farmer Mac's business will likely develop slowly, it could adversely affect the competitive position of Farm Credit institutions if their managers decline to participate in the Farmer Mac program and that program turns out to be attractive to farmers. In selling loans through the secondary market, Farm Credit institutions' competitiveness will depend primarily on the ability to deliver low-cost origination and pooling services.

The Farm Credit institutions are also competitors with the secondary market through their ability to originate and hold mortgage loans funded through the existing Farm Credit Banks. This competition will provide a constraint on the profit levels that can be earned in the secondary market.

BORROWER RIGHTS

Mr. WHITTEN. Last year, Mr. Duncan testified that the Farm Credit examinations have found various violations of regulations concerning borrower's rights provisions, but there apparently had been no intentional violation of the Act. Since last year, has FCA found any deficiencies that warrant regulatory action and enforcement concerning the borrower's rights provisions of the Act?

Mr. STEELE. There were some instances of noncompliance with borrower rights regulations disclosed in calendar year 1989. The violations occurred primarily as the result of inadequate internal controls and a lack of training for the field staffs of FCS institutions as opposed to intentional violations. Requirements to correct the deficiencies identified in the borrower rights area were incorporated in enforcement actions in articles pertaining to the improvement of internal controls, to correct violations of law, or where addressed in supervisory letters sent to the institutions.

LOAN VOLUME OF FARM CREDIT INSTITUTIONS

Mr. WHITTEN. For the record, please provide a table showing the loan volume of Farm Credit institutions over the last 10 years.

Mr. STEELE. I will be happy to provide a table which shows the gross loans outstanding of the combined Farm Credit institutions for the past 10 years.

[The information follows:]

Farm Credit institutions—10-year trend, gross loans outstanding to farmers and cooperatives at Dec. 31 yearend

Yearend:	Amount (in millions)
1989	$50,707
1988	51,427
1987	52,498
1986	58,249
1985	69,805
1984	77,787
1983	81,878
1982	81,383
1981	78,720
1980	70,808

Mr. WHITTEN. During the late 1980's loan volume was falling off drastically at some Farm Credit institutions and severely threatened the financial health of many institutions. Can you please provide us with a general statement as to how the System, itself, is faring at this point?

Mr. STEELE. Developments over the past year have been encouraging. The turnaround in farm real estate values and the strength in farm incomes have bolstered loan collateral and overall credit quality. Although the System's 1989 loan volume generally ran below 1988 levels, it has stabilized near the $50 billion mark in recent quarters and seems poised for some growth in 1990. Both the amount and quality of earnings improved as the banks and associations were able to increase net interest income sharply while reducing the level of nonperforming assets. The System's net income through the third quarter of 1989 was $457 million, somewhat ahead of the year-earlier pace when the System earned $704 million for the year. The chief difference in 1989, however, is that a much larger share of the earnings represented operating profits rather than reversals of loan loss provisions and other one-time adjustments as was the case in 1988. From a longer term perspective, the System still faces the important challenges of rebuilding its capital base to cope with the risks associated with a rapidly changing economic environment and to repay the financial assistance which has been received. To be successful, it must maintain or expand its market share, further improve net interest margins, and reduce operating expenses as much as possible.

OPERATING EXPENSES OF FARM CREDIT SYSTEM INSTITUTIONS

Mr. WHITTEN. The last couple of years the issue of operating expenses incurred by the Farm Credit institutions has been significantly discussed at our hearings. Last year, it was reported that operating expenses by institutions as a percent of loan volume was 1.41 percent during fiscal year 1988, which was a decrease from a high of 1.5 percent in fiscal year 1987. Can you please provide a table showing the operating expenses as a percent of loan volume from 1984 through 1989?

Mr. STEELE. While System loan volume continues to decline (though at a slower pace), the System's progress in reducing operating expenses appears to have slowed. During 1989, total loan volume declined 1.4 percent, compared with the 1988 volume decline of 2 percent, while operating expenses were only reduced by 0.05 percent. The ratio of operating expenses to loan volume for 1989 was 1.45 percent, an increase of 3 basis points, compared with 1.42 percent for 1988, a reduction of 8 basis points from the previous year. A major part of this leveling off in operating expenses can be directly attributed to an increased stability in staffing of System institutions and general inflation factors. As the level of nonperforming assets is brought down, we expect further improvement in operating performance because servicing this part of the portfolio is especially cost intensive.

[The information follows:]

[Dollar amounts in millions]

	Total loan volume	Operating expenses	Operating expenses as percent of loan volume
Year:			
1984	$77,787	$809.1	1.04
1985	69,805	895.9	1.28
1986	58,249	809.9	1.39
1987	52,498	786.1	1.50
1988	51,427	733.7	1.42
1989	50,707	733.3	1.45

Mr. **Whitten**. Please provide for the Committee a table showing the salaries of Farm Credit System CEOs for all districts and entities from 1981 through the current year.

Mr. **Steele**. I will provide a table reflecting this information for banks and service organizations. FCA does not have this information for the 272 associations.

[The information follows:]

Salaries of Farm Credit System CEOs

District/Entity	1981	1982	1983	1984	1985	1986	1987	June 1988	February 1989	March 1990
Springfield	(a) $106,000	122,500	134,750	148,225	170,000	178,500	132,000	132,000	165,488	180,000
Baltimore	(a) $106,800	120,000	138,000	147,600	163,836	168,000	185,000	185,000	(g) 193,750	193,750
Columbia	(b) $114,529	130,563	154,100	162,000	(a) 189,750	189,750	189,750	189,750	(g) 150,000	150,000
	(c) $96,250	106,000	118,000	134,000	---	---	---	---	---	---
Louisville	(d) $85,500	100,890	106,000	(b) 160,000	165,000	(a) 146,000	146,000	146,000	(g) 154,760	140,500
	(e) $85,000	125,000	131,250	---	---	---	---	---	---	---
	(c) $110,750	121,750	127,750	140,000	125,000	---	---	---	---	---
Jackson	(d) $85,000	85,000	98,000	107,800	118,580	(a) 140,000	140,000	140,000	Receiver	Receiver
	(e) $74,900	85,386	98,000	105,840	116,424	---	---	---	(e) 97,500	102,375
	(c) $89,947	90,000	90,000	96,300	105,930	---	---	---	---	---
St. Louis	(d) $93,000	107,000	115,000	(a) 150,000	162,000	160,000	160,000	160,000	(g) 160,000	160,000
	(e) $90,000	103,500	110,000	---	---	---	---	---	---	---
	(c) $80,000	80,000	85,000	---	---	---	---	---	---	---
St. Paul	(d) $105,000	90,000	(a) 149,250	161,190	180,000	180,000	195,000	195,000	(g) 195,000	195,000
	(f) $128,000	140,800	---	---	---	---	---	---	(c) ---	127,300
Omaha	(d) $104,000	114,000	128,000	(a) 150,000	160,000	160,000	180,000	180,000	(g) 195,000	195,000
	(e) $100,000	110,000	123,000	---	---	---	---	---	---	---
	(c) $96,000	106,000	119,000	---	---	---	---	---	---	---

Legend:
(a)= Joint Bank CEO
(b)= FLB/FICB
(c)= BC
(d)= FLB
(e)= FICB
(f)= FICB/BC
(g)= Merged Bank (July 1988)
(h) = New Bank

Salaries of Farm Credit System CEOs Continued

District/Entity	1981	1982	1983	1984	1985	1986	1987	June 1988	February 1989	March 1990
Wichita	(d) $80,000	90,000	100,800	108,000	(a) 146,000	146,000	180,000	(vacant)	(g) 146,000	158,000
	(e) $82,500	87,500	100,000	108,000	---	---	---	---	---	---
	(c) $75,000	85,000	95,200	84,000	---	---	---	---	---	---
Texas	(d) $80,000	91,200	102,000	(a) 140,000	140,000	144,000	(d) 115,000	115,000	(g) 142,000	152,800
	(e) $75,900	86,550	98,500	---	---	---	(e) 103,000	103,000	---	---
	(c) $78,500	87,925	98,475	---	---	---	(c) 115,000	115,000	---	---
Sacramento	(d) $85,000	96,000	103,000	115,000	(a) 180,000	170,000	157,500	157,500	(g) 146,000	178,200
	(f) $123,800	136,000	144,000	158,000	---	---	---	---	---	---
Spokane	(d) $96,000	111,360	92,000	98,500	(a) 130,000	130,000	130,000	130,000	(g) 130,000	160,000
	(e) $95,000	106,400	92,000	100,500	---	---	---	---	---	---
	(c) $94,250	106,000	85,000	90,000	---	---	---	---	---	---
Central Bank For Cooperatives	$114,000	127,600	137,100	148,060	163,000	167,890	178,000	178,000	Merged	---
National Bank for Cooperatives	---	---	---	---	---	---	---	---	(h) 225,000 (1/1/89)	225,000
Farmbank Services	$88,500	93,800	82,500	87,500	Abolished	---	---	---	---	---
Funding Corporation	$127,600	150,568	168,625	185,500	205,900	216,000	180,000	180,000	195,000	350,000
Farm Credit Corp of America	---	---	---	---	---	270,000	270,000	270,000	153,750	Merged
Farm Credit System Capital Corporation	---	---	---	---	---	---	250,000	Abolished	---	---
Farm Credit System Leasing Corporation	---	---	---	---	---	unknown	unknown	156,000	unknown	unknown

Legend:
(a)= Joint Bank CEO
(b)= FLB/FICB
(c)= BC
(d)= FLB
(e)= FICB
(f)= FICB/BC
(g)= Merged Bank (July 1988)
(h) = New Bank

CEASE AND DESIST ORDERS

Mr. **Whitten**. During calendar year 1989, did the Farm Credit Administration execute any cease and desist orders? If so, how many and what was the general purpose for most of these?

Mr. **Steele**. Yes, the Farm Credit Administration did issue thirteen cease and desist orders during calendar year 1989. One was a new cease and desist order dealing with the safety and soundness of an institution. Three were issued to replace supervisory conditions of merger that had been placed on some of the district Farm Credit Banks as a result of the merger of a Federal Land Bank and a Federal Intermediate Credit Bank, where one or both of the banks were operating under previous enforcement actions. Five were issued to replace existing cease and desist orders by incorporating new findings. Four were issued to upgrade the type of supervisory action on the institution due to increased concern regarding the operations of the institution.

REGULATORY ACCOUNTING PRACTICES

Mr. **Whitten**. On October 4, 1988, the FCA Board adopted final amendments to the regulations relating to the Regulatory Accounting Practices [RAP]. The most significant amendment was authority to extend the use of RAP until 1992. Are there any Farm Credit institutions still using RAP?

Mr. **Steele**. The FCA no longer requests information on the utilization of RAP by Farm Credit institutions in its call reporting requirements; the use of RAP is reviewed on an institution-by-institution basis through the examination process. This is because the 1987 Act removed the primary motivation for the utilization of RAP, which was to enable institutions to continue to operate in the normal course of business and retire their stock at par value even though it was worth less than par value under generally accepted accounting principles [GAAP]. The only remaining benefit is that RAP may be used by Farm Credit institutions in evaluating interest rates charged on loans.

ASSESSMENT FORMULA

Mr. **Whitten**. Last year FCA was in the final phases of an analysis to revise the agency's assessment formula to System institutions. Could you please provide us with the details of any changes recommended by that analysis and the impact to the institutions?

Mr. **Steele**. The proposed formula, which was in part based on the assets of an institution, was affected when some but not all of the banks began transferring their assets to the associations. Because inequities would have resulted from the application of that formula, we are now re-examining the whole issue.

FARM CREDIT ADMINISTRATION SALARIES

Mr. **Whitten**. It has been reported the last few years that the FCA was unable to compete with such agencies as FDIC, Comptroller of the Currency, and others because they were able to pay salaries differently than FCA. Has anything been done to address that issue?

Mr. STEELE. Yes. For some time, the other financial regulators have exercised their special authorities to provide enhanced compensation to their employees. In the Financial Institutions Reform, Recovery, and Enforcement Act of 1989—FIRREA, the Congress strengthened these authorities with the condition that the regulators maintain comparability with each other. FCA was included in these compensation provisions. Knowing the actions already taken by the other financial regulators, but conscious of its overall budget limitations, FCA made some modest improvements in its compensation program which were effective at the beginning of this calendar year. The specifics have been provided in response to an earlier question. In summary, we started providing a cost-of-living differential at four of the 12 FCA duty station locations, and we increased the FCA salary schedule 3 percent above the General Schedule. These actions were taken to address part of the problem, but do not achieve comparability with other Federal financial regulators.

However, because of a technical error in FIRREA, one provision was omitted that dealt with FCA's senior executive service personnel. That provision is included in H.R. 2869, which has passed the House and is awaiting Senate action.

FARM CREDIT ADMINISTRATION BUDGET—HEADQUARTERS VS. FIELD

Mr. WHITTEN. Of the total fiscal year 1990 expenses, $36,120,000, what percent is allocated to FCA headquarters activities versus field activities?

Mr. STEELE. A more meaningful comparison would be the percentage of expenses devoted to our primary function of supervision versus administrative expenses used to support supervisory activities. Supervisory activities including examination, examiner training, enforcement, financial reporting and analysis, litigation, and direct field support constitute approximately 86 percent of the FY 1990 budget.

Mr. WHITTEN. For the record, please provide a table showing permanent positions by grade and staff year and field or headquarters activity.

Mr. STEELE. I will provide, for the record, a table showing permanent positions by grade and staff-year and field or headquarters activities versus field activities.

[The information follows:]

Organization	Executive	SES	VG-15	VG-14	VG-13	VG-12	VG-11	VG-10	VG-9	VG-8	VG-7	VG-6	VG-5	VG-4	VG-3	VG-2	Supervision/ administration (percent)
Office of the Board	2		2			1			1		1						(¹)
OCPA			1	1					1			1					(¹)
OGC		2	2	1	1	2	1				1	1					(¹)
			2	1	2		1		1			1					(²)
OIG		2		5					1								(¹)
OE		5	13	38	52	70	67		31	3	30	12	17	5			(²)
ORE		1	6	3	1	1			1		1						(²)
OFA		2	7	8	7	2	5		1	1	4	2					(²)
ORM		2	6	12	9	9	2		9	3	18	5	10	10	1		[3] 69, [1] 31

[1] Administration.

[2] Supervision.

[3] ORM staff are not solely dedicated to either supervision or administration activities. The percentage breakouts are based on the budget allocations for supervision and administration activities.

Mr. Whitten. Testimony before the committee in previous years shows a great concern by FCA with the overhead costs of the System which, in part, have caused some of the financial problems to both the System and the farmer. With the Farm Credit Administration, Assistance Board, Farm Credit Corporation of America and several others operating from System finances, do you believe that providing a 15-percent increase for FCA headquarters staff is consistent with these concerns.

Mr. Steele. In the past 3 fiscal years, the budget for FCA has increased only 3.2 percent. The increase for FY 1991 is for all operating expenses nationwide, not just the McLean office. The budget reflects the resources required to address critical issues facing the agency, a reinstatement of line items reduced, deferred, or canceled for FY 1990, and the funds necessary to attempt to maintain limited pay comparability with other financial regulators in accordance with Public Law 101-73, the Financial Institutions Reform, Recovery, and Enforcement Act of 1989. We believe the increase is consistent with FCA's mandate to protect borrowers through ensuring the safety and soundness of the System.

The Farm Credit System Assistance Board was created by Congress to carry out functions different from FCA's. The Farm Credit Corporation of America, which has now merged with the Farm Credit Council, was created by System institutions themselves.

Mr. Whitten. Do you have any statistics to show the turnover by FCA examiners over the last four years?

Mr. Steele. I will provide a list of turnover rates for FCA examiners in calendar years 1986, 1987, 1988, and 1989.

[The information follows:]

	Percent
1986	20.5
1987	18.6
1988	12.3
1989	15.2

PREDATORY PRICING

Mr. Whitten. During fiscal year 1988 and early fiscal year 1989 the question of predatory interest rate pricing was an issue within lending communities. Is the FCA still receiving inquiries and complaints from other lenders regarding this loan pricing?

Mr. Steele. The numbers of complaints have diminished significantly in the latter half of 1989. FCA includes loan pricing practices within the scope of each examination. These examinations have criticized some institutions for failing to price loans in accordance with risk and for not having done adequate surveys of competitive lending rates. Individual complaints have been investigated when the information provided warranted an investigation. These investigations have identified instances where Farm Credit institutions were offering rates below neighboring commercial banks, but have not supported claims that Farm Credit institutions were pricing loans below their cost of funds. In these cases, the FCA has taken action and Farm Credit institutions have adjusted their rates accordingly.

ACQUIRED PROPERTY

Mr. **Whitten**. Please provide for the record a five-year table of the System's property acquired through foreclosures or voluntary conveyances.

Mr. **Steele**. I will be happy to provide a table which presents combined information available to the agency from individual Farm Credit institutions. The agency did not collect data on acquisitions and sales until 1988, starting with 1987 data. The sales and acquisitions will not necessarily reconcile with yearend inventory due to adjustments for losses and depreciation.

[The information follows:]

VALUE OF ALL REAL ESTATE AND OTHER ACQUIRED PROPERTY NET OF ALLOWANCE FOR LOSSES

[In thousands of dollars]

	Acquisitions	Sales	Yearend inventory
Year:			
1985	N/A	N/A	940,513
1986	N/A	N/A	1,101,463
1987	1,122,908	1,281,408	876,292
1988	720,529	950,835	618,020
1989	441,874	626,550	468,350

LOAN PERFORMANCE

Mr. **Whitten**. Please provide for the record a table of the elements of the System showing, by Farm Credit District, the most recent information on the percentage of total value of loans classified as performing, restructured, whether high-risk or nonaccrual.

Mr. **Steele**. I will provide that information for the record.

[The information follows:]

Table 1 reflects the most current information available to the FCA on nonperforming loans by Farm Credit district with totals and percentages by type of institution. Nonperforming includes all loans not meeting the original terms and conditions of the loan contract.

NON-PERFORMING LOANS AT DECEMBER 31, 1989

[In millions of dollars]

	Performing	Restructured	Other high risk	Nonaccrual	Total
A. Farm credit banks: [1]					
Springfield	1,425,425	0	0	3,695	1,429,120
Baltimore	2,602,523	8,111	7,623-	5,556	2,623,813
Columbia	3,758,539	22,289	64,513	163,555	4,008,896
Louisville	3,313,507	0	0	0	3,313,507
Jackson FLB	98,815	28,279	20,742	138,962	286,798
Jackson FICB	440,404	0	0	1,861	442,265
St. Louis	2,960,374	96,995	86,523	259,349	3,403,241
St. Paul	3,649,542	1,116,799	778,349	406,505	5,951,195
Omaha	3,101,249	470,261	51,970	94,500	3,717,980
Wichita	3,060,278	165,631	40,229	217,744	3,483,882
Texas	3,285,986	30,373	227,624	175,129	3,719,112
Sacramento	3,554,702	157,552	1,295,659	297,393	5,305,306

NON-PERFORMING LOANS AT DECEMBER 31, 1989—Continued

[In millions of dollars]

	Performing	Restructured	Other high risk	Nonaccrual	Total
Spokane	1,941,786	28,912	422,537	400,652	2,793,887
13 bank total	33,193,130	2,125,202	2,995,769	2,164,901	40,479,002
Loan volume as a percentage of total	82.00	5.25	7.40	5.35	100.00
B. Banks for coperatives: [2]					
Springfield	133,740	0	0	0	133,740
St. Paul	905,127	28	8,942	4,398	918,495
NBC	9,367,343	85,849	162,802	8,139	9,624,133
3 bank total	10,406,210	85,877	171,744	12,537	10,676,368
Loan volume as a percentage of total	97.47	0.80	1.61	0.12	100.00
C. Farm credit associations: [3]					
Springfield	1,564,130	2,834	18,283	2,059	1,587,306
Baltimore	2,654,661	10,017	64,553	16,086	2,745,317
Columbia	768,262	12,853	13,789	33,264	828,168
Louisville	2,979,833	172,801	110,125	194,545	3,457,304
Jackson	388,200	1,601	23,465	17,686	430,952
St. Louis	562,206	10,996	4,300	12,523	590,025
St. Paul	1,219,842	196,862	161,974	51,071	1,629,749
Omaha	475,933	39,908	1,565	9,551	526,957
Wichita	503,712	13,333	13,979	11,212	542,236
Texas	663,805	1,153	45,293	28,749	739,000
Sacramento	1,711,237	66,324	150,742	93,764	2,022,067
Spokane	327,104	5,488	21,508	24,891	378,991
12 district total	13,818,925	534,170	629,576	495,401	15,478,072
Loan volume as a percentage of total	89.28	3.45	4.07	3.20	100.00

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[1] FCB's (1) mortgage loans to farmers in areas served by Federal Land Bank Associations and (2) loans to Federal Land Credit Associations and Agricultural Credit Associations and Production Credit Associations which then lend to farmers.

[2] BC's lend to Farmer Cooperatives and their affiliates.

[3] Federal Land Credit Associations, Production Credit Associations and Agricultural Credit Associations lend to farmers. Federal Land Bank Associations act as agents for Farm Credit Banks, which carry the mortgage loans to farmers.

Note.—The total exceeds the net loans outstanding to farm and cooperative borrowers. This is because Farm Credit banks lend to associations, which are direct lenders, as well as to farmers through associations, which are not direct lenders.

OFFICIAL RECEPTION AND REPRESENTATION EXPENSES

Mr. WHITTEN. What was the amount spent in fiscal years 1987, 1988 and 1989 for official reception and representation expenses?

Mr. STEELE. In fiscal years 1987, 1988, and 1989, the FCA spent $10,355.48, $1,429.32, and $933.13, respectively, for official reception and representation expenses.

Mr. WHITTEN. Are any of the funds in the Farm Credit Building Association Account used for representation or receptions?

Mr. STEELE. No.

FOREIGN TRAVEL

Mr. WHITTEN. For the record, please list all foreign travel by any staff of the Farm Credit Administration during fiscal year 1989. Please provide for the record the name of the employee, the location, the cost, the length of stay and the purpose of each trip.

Mr. STEELE. There was no foreign travel by FCA staff in fiscal year 1989 paid by FCA. Dr. George Irwin, Deputy Director, Office of Financial Analysis, served as a member of a study team to

Poland in August. His expenses were paid by the Foundation for the Development of Polish Agriculture.

OBJECT CLASS EXPENSES

Mr. WHITTEN. Please provide for the record an object class table for fiscal years 1989, 1990 and 1991.

Mr. STEELE. I will provide an object class table for FY 1989-1991, for the record.

[The information follows:]

FARM CREDIT ADMINISTRATION
FY 1991 Object Class Schedule
Proposed Budget
(in thousands of dollars)

OBJECT CLASS	TOTAL	OFFICE OF THE FCA BOARD	OFFICE OF CONGRESSIONAL & PUBLIC AFFAIRS	OFFICE OF EXAMINATION	OFFICE OF FINANCIAL ANALYSIS	OFFICE OF GENERAL COUNSEL	OFFICE OF RESOURCES MANAGEMENT	OFFICE OF INSPECTOR GENERAL	OFFICE OF REGULATORY ENFORCEMENT
Personnel compensation....................	26,543	794	460	14573	2766	1385	4896	513	1,156
Personnel benefits........................	6,075	221	89	3606	609	271	897	127	255
Travel and transportation of persons.......	4,234	69	6	3506	68	66	395	17	107
Transportation of things..................	114	0	0	4	0	0	110	0	0
Communications, utilities, and other rent..	996	0	0	39	0	0	957	0	0
Printing and reproductions................	192	0	0	5	0	0	187	0	0
Other services............................	2,015	52	10	188	172	38	1531	10	14
Supplies and materials....................	623	0	2	106	2	0	512	1	0
Equipment.................................	756	15	4	92	4	0	636	5	0
Total obligations....................	41,548	1,151	571	22,119	3,621	1,760	10,121	673	1,532

FARM CREDIT ADMINISTRATION
FY 1990 Object Class Schedule
Approved Budget
(in thousands of dollars)

OBJECT CLASS	TOTAL	OFFICE OF THE FCA BOARD	OFFICE OF CONGRESSIONAL & PUBLIC AFFAIRS	OFFICE OF EXAMINATION	OFFICE OF FINANCIAL ANALYSIS	OFFICE OF GENERAL COUNSEL	OFFICE OF RESOURCES MANAGEMENT	OFFICE OF INSPECTOR GENERAL	OFFICE OF REGULATORY ENFORCEMENT
Personnel compensation......................	23,022	471	214	13,676	2,043	1,042	4,226	470	880
Personnel benefits..........................	5,332	100	31	3,591	381	192	741	121	175
Travel and transportation of persons.......	3,629	61	5	3,009	48	57	341	14	93
Transportation of things....................	109	0	0	58	0	0	51	0	0
Communications, utilities, and other rent..	868	0	0	36	1	0	832	0	0
Printing and reproductions..................	168	0	0	5	0	0	163	0	0
Other services..............................	1,712	169	8	117	114	108	1,181	10	5
Supplies and materials......................	649	0	0	82	2	1	562	1	1
Equipment...................................	631	1	0	15	5	0	606	0	3
Total obligations......................	36,120	803	259	20,588	2,595	1,400	8,703	616	1,157

FARM CREDIT ADMINISTRATION
FY 1989 Object Class Schedule
Actual Obligations
(in thousands of dollars)

OBJECT CLASS	TOTAL	OFFICE OF THE FCA BOARD	OFFICE OF CONGRESSIONAL & PUBLIC AFFAIRS	OFFICE OF EXAMINATION	OFFICE OF FINANCIAL ANALYSIS	OFFICE OF GENERAL COUNSEL	OFFICE OF RESOURCES MANAGEMENT	OFFICE OF INSPECTOR GENERAL	OFFICE OF REGULATORY ENFORCEMENT
Personnel compensation....................	20,857	390	312	12,784	1,850	886	3,537	384	714
Personnel benefits........................	3,315	57	39	2,131	277	126	512	66	108
Travel and transportation of persons.......	3,867	27	4	3,377	68	31	275	10	77
Transportation of things..................	22	0	0	7	0	0	15	0	0
Communications, utilities, and other rent..	871	0	3	28	1	1	837	0	1
Printing and reproductions................	166	0	0	4	0	0	162	0	0
Other services............................	1,100	89	5	45	73	30	842	8	8
Supplies and materials....................	640	1	1	138	40	0	439	2	10
Equipment.................................	3,390	17	1	308	132	19	2,864	19	30
Total obligations....................	34,228	580	365	18,822	2,441	1,100	9,482	490	949

APPROVALS BY ACTING CHAIRMAN

Mr. WHITTEN. Please provide for the record a list of the FCA Acting Chairman's approvals that occurred under the F.C. Order #888 during fiscal year 1989.

Mr. STEELE. Farm Credit Administration Order No. 888 was adopted by the FCA Board on January 6, 1989, to ensure the FCA was able to operate effectively in carrying out its statutory duties during the period of time in which the FCA Board was without a quorum of members. I will provide a list which shows what the FCA's Acting Chairman, under such delegated authority, decided during fiscal year 1989.

[The information follows:]

Enforcement-related actions	19
Charter-related actions	43
Corporate activity-related actions, such as equity retirements	14
Agency-related actions	21
Receivership actions	3
FCS Building Association actions	1
Total	101

FCS BUILDING ASSOCIATION

Mr. WHITTEN. Please provide for the Committee a breakout in terms of revenues and expenditures related to the Farm Credit System Building Association budget estimate for fiscal years 1990 and 1991.

Mr. STEELE. I will provide the breakout of revenues and expenditures in the 1990 and 1991 FCS Building Association budget estimates for the record.

[The information follows:]

[In dollars]

	1990	1991
Revenues:		
Farm credit system assessments	3,300,000	3,300,000
Farm credit building tenant rent	700,000	750,000
Communications administration (NET) (building phone system administration)	85,000	100,000
Interest (net)	65,000	75,000
Total revenues	4,150,000	4,225,000
Expenditures—property management:		
Real estate tax	395,000	413,000
Utilities	250,000	240,000
Insurance	40,000	40,000
Building services	615,000	625,000
Elevator maintenance	(8,000)	(8,000)
Extermination	(3,000)	(3,000)
Security guards	(135,000)	(137,000)
Electronic security	(30,000)	(30,000)
Grounds/interior plant maintenance	(62,000)	(60,000)
Safety system	(25,000)	(25,000)
Engineering	(125,000)	(130,000)
Refuse/snow removal	(17,000)	(17,000)
Cleaning	(175,000)	(180,000)
Legal/administration	(15,000)	(15,000)
Repairs	(20,000)	(20,000)

[In dollars]

	1990	1991
Management fees (to administer above)	80,000	82,000
Subtotals	1,380,000	1,400,000
Building Association:		
Contract services	190,000	192,000
Audit and taxes	(62,000)	(62,000)
Legal services	(18,000)	(20,000)
Electrical/mechanical	(50,000)	(50,000)
Phone system	(40,000)	(40,000)
Audio, files, rest room, computer room cleaning and maintenance	(20,000)	(20,000)
Maintenance program	(170,000)	(152,000)
Equipment/parts/installation	(50,000)	(38,000)
Carpet and installation	(20,000)	(15,000)
5-year paint/refinish	(50,000)	(46,000)
Normal maintenance average	(50,000)	(53,000)
Personnel compensation and benefits	145,000	156,000
Community and business (FCS int., assets, etc.)	5,000	5,000
Training and travel (10 trips-inventory-training-cabling)	15,000	20,000
Personal property tax	90,000	90,000
Supplies/equipment	25,000	25,000
Subtotal	640,000	640,000
Field office expenditures (leases, furnishings, administration, 11 field offices)	2,025,000	2,150,000
Total expenditures	4,045,000	4,190,000

FEDERAL LAND BANK OF JACKSON IN RECEIVERSHIP

Mr. WHITTEN. Please provide some details into the current status of the former Jackson District Land Bank. Please discuss both the long-term and short-term borrowing ability of farmers in the former Jackson District.

Mr. STEELE. The Federal Land Bank of Jackson in Receivership's (FLBJR) total assets at December 31, 1989, were $566 million, down 58 percent from the $1.3 billion of a year earlier. During the same period, the FLBJR substantially reduced its number of employees from 350 to 100. A single $1.1 billion sale of loan assets to the Farm Credit Bank of Texas was completed in February 1989 and was the primary reason for the FLBJR's success in meeting its business plan objectives for 1989.

A second bulk sale of assets was offered by the FLBJR in June 1989 to the district banks of the Farm Credit System. This offering did not result in a sale, and the receivership continued marketing the remaining assets. Through private negotiations, a total of 248 loans with contractual debt obligation exceeding $15 million were sold to the Farm Credit Bank of Texas in November. During 1989, the receivership staff also worked with individual borrowers through refinancing, restructuring, and compromises to settle 304 accounts for $122.3 million. Also during 1989, 627 foreclosures and 482 bankruptcies were handled by the FLBJR. Properties acquired through the loan liquidation process were sold at two series of auctions held in the spring and fall of 1989. Individual sales were also made continually throughout the year. Four hundred and forty-six properties valued in excess of $52.7 million were sold.

The Farm Credit Administration Board and the Board of Directors of the Farm Credit System Insurance Corporation have approved an agreement in principle for the sale of the majority of the remaining assets of the receivership to banks of the Farm Credit System. The banks are to assume a like amount of bonded indebtedness, with the Farm Credit System Financial Assistance Corporation providing assistance to relieve the deficit between the value of the remaining assets and outstanding liabilities. Approval of the agreement in principle was granted after receipt of a recommendation by the receivership that the proposed transaction would be beneficial to the receivership estate. While approval is required by each of the banks' boards of directors and the Farm Credit System Assistance Board, the Farm Credit Administration is hopeful the transaction will be consummated by June 1, 1990. After June 1, the receivership operation would be largely diminished and directed toward liquidating a small amount of remaining assets, completing some litigation, and the overall administrative winding down of the receivership operation.

The Farm Credit Administration has chartered six Federal Land Bank Associations to provide long-term credit to borrowers in the three-state territory formerly served by the FLBJR. All of these associations are stockholders of the Farm Credit Bank of Texas. The short-term borrowing needs of farmers were unaffected by the failure of the Federal Land Bank of Jackson. The Federal Intermediate Credit Bank of Jackson and existing Production Credit Associations continue to provide short-term credit to borrowers. In early 1990, a Federal court affirmed the FCA's ruling that, under the law, the Federal Intermediate Credit Bank of Jackson was required to merge with the Farm Credit Bank of Texas, which is serving the territory previously served by the FLB of Jackson.

REQUESTS OF ASSOCIATIONS TO CHANGE DISTRICTS

Mr. WHITTEN. We know that several PCAs requested approval to change districts prior to the January 1989 filing deadline. Please provide a status of these requests.

Mr. STEELE. A total of 31 petitions requesting approval to change districts were filed with FCA on or before the January 5, 1989 deadline. Of this number, 19 were petitions from PCAs. Petitions from eight PCAs were determined eligible for reassigment under section 433 of the Agricultural Credit Act of 1987. These were Albuquerque PCA, PCA of Eastern New Mexico, PCA of Southern New Mexico, Eastern Idaho PCA, Great Plains PCA, South Central Oklahoma PCA, Clinton PCA, and PCA of Woodward. The remaining petitions were determined ineligible for one of two reasons; either the association did not adjoin another district as of the date of enactment of the 1987 Act; or the stockholders had imposed a condition in their petition that the reassignment would not be pursued unless it was pursued by other state associations whose territory was not adjoining, thus imposing a condition that could not be met.

Of the eight eligible PCA petitions, one association (Great Plains) failed to receive the required approval from the adjoining district's Farm Credit Bank; three (South Central Oklahoma, Clinton, and

Woodward) have not yet submitted proposed stockholder disclosure material to the FCA for review and approval; three (Eastern New Mexico, Southern New Mexico, and Albuquerque) have been given preliminary approval by the Farm Credit System Assistance Board and a conditional approval by the FCA; and one (Eastern Idaho) has not yet been acted on by the FCA, pending approval by the Farm Credit System Assistance Board (FCSAB) and receipt by the FCA of an updated proposal with current financial information. FCSAB approval is necessary because the district has stated its intention to apply for financial assistance. Of the three PCAs receiving conditional approval, one association (Albuquerque) has since resubmitted its proposal to FCA for confirmation that the conditions have been satisfied, and this review is underway.

Mr. WHITTEN. Mrs. Smith?

Mrs. SMITH. Thank you, Mr. Chairman.

Let me say welcome to both of you. We're so glad you're here, and I'm delighted that you are both long time friends of mine and that you have a great personal background in agriculture.

That certainly ought to make you just ideal for the positions you hold. I want all the committee to know that Mr. Steele and I were on the National Board of the American Farm Bureau Federation together at the same time for a number of years.

I have just three or four questions that I'd like to ask of each of you. I still get, Mr. Steele, comments as I go across Nebraska from constituents about predatory pricing?

I wanted to ask you if you have any documented cases of predatory pricing, if you're still continuing to follow that situation, and what you would do if you found predatory pricing.

Mr. STEELE. Thank you, Mrs. Smith. I'm pleased that you asked the question, because it does come before us on occasion.

I also recall that shortly after I raised my right hand and took the oath of office for my current position, I had a short honeymoon before I was in your office with some bankers from your native State of Nebraska.

As a matter of fact, Mr. Thor and I were both there. We were indoctrinated the same day. Commercial bankers are indeed very concerned, and I should like to answer your question by emphatically saying that the Farm Credit Administration, in its performance of its duties, watches very closely and monitors very closely any suggestion of predatory pricing.

Whenever we receive allegations of predatory pricing, we immediately ask the author to give us any available evidence so that we can go to a specific area or a specific association and investigate specifically.

In all instances, we do have examiners go to that area, and we have not once yet, in all of our examinations, made discovery of predatory pricing.

We do know that there are certain borrowers that are given preferential rates because they use only a small percentage of the equity value of that loan, and they're very low risk loans.

But predatory pricing, no, ma'am, but we follow each one through carefully.

Mrs. SMITH. I appreciate that careful answer very much, and I think you will both be interested that just before I came here I met with the LEAD people of Nebraska.

Now, LEAD is a State educational organization for agricultural leaders. You have to be under 40 to be in it, and they are selected very carefully.

One of them, who is also a country banker, said he thought you carried on predatory pricing. He felt that we didn't need the Farm Credit System anymore.

So I said how many of you, and there were 41, think that we don't need the Farm Credit System anymore, two raised their hands.

Everybody else raised their hand we want to keep you. So much for that. You know, the last few years, Mr. Steele, has been relatively good in agriculture.

Land values have gone up, our income has gone up. Overall, has the Farm Credit System, or have the banks, rather, strengthened with the agricultural economy? What's your outlook for the Farm Credit System?

Mr. STEELE. My outlook is based upon the current year where we have seen the banks, as a total entity, grow in their financial strength through added reserves.

We have seen the Farm Credit System grow in numbers of new loans, and we've also seen a depletion of non-accrual loans.

There are still problems with farmers and ranchers, and thus there are still problems with the banks. This is true in certain geographic areas more so than in others.

So there are some very careful processes that need to continue. As the Chairman brought up, we are sending a lot of checks from the Federal Government to farmers, and I trust that as we see those subsidies change, this could have a difference upon some of those non-accrual loans and their ability to pay.

So it's a sobering time. The problem isn't over, but things are better. We are, in fact, heading in the right direction.

Mrs. SMITH. Thank you for that answer. Now I'd like to ask a question about the Farmer Mac. We're all aware of the difficult times Congress has faced in trying to develop a secondary market for our agricultural loans, and I'm pleased that Farmer Mac was authorized in the Agricultural Credit Act of 1987.

However, implementation of the Farmer Mac continues to go at a slow and disappointing pace. Could you update the subcommittee on the progress that is being made in getting Farmer Mac up and running?

Is it going to prove successful and meet the expectations we had when we authorized it?

Mr. STEELE. Yes. The Farm Credit Administration, at this very moment, is examining Farmer Mac. The Farm Credit Administration has, for many months, has done much preparatory work in establishing regulations so that Farmer Mac can proceed.

As to whether or not it will succeed will depend to a great extent upon how the small commercial banks throughout the agricultural areas of our United States participate.

Many of the Farm Credit System banks have formed pools. Six of the banks have gone together for a pooling operation, and I suspect other banks will participate, as well as associations.

But it will take more than this participation to cause it to succeed, and I think, again, it depends upon the kind of viability and determination and participation by the other commercial banks that are involved in agricultural lending.

Only then will we see if it's going to succeed. I do believe, as I've talked to some of the commercial bankers, both through the American Bankers Association and some of the State bankers associations, there is a continuing interest and keenness in looking at it carefully, and many are going to participate. Time will tell.

BUDGET INFORMATION—15-PERCENT INCREASE

Mrs. SMITH. Mr. Steele, I understand that for fiscal year 1991 the FCA has requested a substantial increase of $5.4 million to bring their FY91 spending to $41.548 million. FY90 spending levels were approved at $36.12 million.

Of the $5.4 million increase, $3.4 million would be used for personnel salary increases. As well, FY91 travel budgets would be increased to $4.2 million compared to $3.6 million in FY90.

As well, personnel benefits for civilians employed by the agency would be increased in FY91 to $6 million compared to $5.3 million in FY90.

Would you please explain to the subcommittee the need for this budget increase? Is the FCA currently suffering staffing and administrative difficulties in light of tight budgets of recent years?

Mr. STEELE. As you have noted, the greatest part of our budget increase is related to salaries and benefit costs, which are driven by salaries. The budget increase for salaries reflects the continuation of modest improvements in the FCA employee compensation program, which were implemented at the beginning of this calendar year, and a return to optimum staffing levels. In January, we initiated a cost-of-living differential for employees at four of the 12 FCA duty stations and increased the FCA salary schedule 3 percent above the Government General Schedule. These compensation improvements were made well after actions by our financial regulatory peers and in response to the direction of Congress in the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, along with enhanced compensation authority for financial regulators, to maintain comparability with each other. Conscious of our budget limitation, our actions were conservative. Nevertheless, it has taken extraordinary measures to accommodate these compensation actions in FY 1990. Currently, we are about 10 percent below our normal staffing level, and a hiring freeze, implemented in December, probably will be necessary for the remainder of FY 1990. All budget categories have been examined and reduced to the barest levels necessary to accomplish our congressional mandate. Acquisitions have been deferred.

In FY 1991, we must recover. We must return to our appropriate staffing level, reinstitute delayed programs, and acquire those items deferred. One year of severe budget restraints has not seriously harmed our ability to assure the safety and soundness of the

Farm Credit System. Continuation of our present austere conditions, however, would place that responsibility in jeopardy.

FCA examiners, over half of the FCA staff, travel 60–70 percent of their official time. Travel is a routine requirement of their work. Travel expenses for FCA will increase in FY 1991 because of a variety of uncontrollable factors, given the essential nature of agency travel. Increases in Government per diem rates, increased lodging costs, airline fares, and mileage allowances are all part of the equation.

For FY 1988 through FY 1990, the FCA budget limitation was increased only 3.2 percent. For FY 1991, expenses for other than salaries, benefits, and travel represent about 11 percent of the requested budget. This represents a continuous decrease from 24 percent in FY 1985. Institutional costs have been reduced to essentials or below that which is adequate for staff support. The FY 1991 budget request is necessary to put the agency back on the road to more normal operations.

JACKSON DISTRICT—GLOBAL SOLUTION

Mrs. **Smith**. The Congress continues to hear a number of complaints regarding the still pending Jackson District situation. Many would like to see an end to the continuing receivership.

Mr. Steele, can you report to the subcommittee at this time any progress regarding the Jackson receivership? Might a final conclusion be reached in the near future?

Mr. **Steele**. On February 27, 1990, the Farm Credit Administration Board and the Board of Directors of the Farm Credit System Insurance Corporation approved an agreement in principle for the sale of the majority of the remaining assets of the receivership to banks of the Farm Credit System. The banks are to assume a like amount of bonded indebtedness, with the Farm Credit System Financial Assistance Corporation providing assistance to relieve the deficit between the value of the remaining assets and outstanding liabilities. The approval of the agreement in principle was granted after receipt of a recommendation by the receivership that the proposed transaction would be beneficial to the receivership estate. While approval is required by each of the banks' boards of directors and the Farm Credit System Assistance Board, the Farm Credit Administration is hopeful the transaction will be consummated. The current timetable contemplates closing to occur no later than June 1, 1990. After June 1, the receivership operation would be largely diminished and directed toward liquidation of a small amount of remaining assets, completion of litigation, and overall administrative winding down of the receivership operation.

EXPANDED SERVICES—I.E., CREDIT CARDS, CHECKING ACCOUNTS

Mrs. **Smith**. Last year, various Farm Credit Banks had proposed expanding the current services they provide to customers. Some had suggested incorporating credit cards and checking accounts into their customer services.

Currently, Mr. Steele, are you aware of any banks' considering this expansion of services? Will the FCA be reviewing any such expansions in services to make certain that they are within the authorization of current law?

Mr. STEELE. It is true that various Farm Credit System institutions have explored the benefits and possibilities of providing additional financial services. However, to date the FCA has not received a request from any Farm Credit institution for the authority to provide such services.

The Farm Credit System banks, under the provisions of 12 CFR 618.8000(c), are required to submit to FCA for approval any proposed new or revised technical assistance or financially related services program offered in the individual districts. As one of the conditions required for FCA consideration of new or revised services programs the applicant is required to state the legal basis for offering such services. Therefore, any proposal for new or revised financially related services programs must be approved by the FCA. The legality of the program, its economic feasibility, staff resource availability, and operational impact are factors that are considered by the FCA in granting approval.

INSURANCE FUND

Mrs. SMITH. As provided in the Agricultural Credit Act of 1987, the Farm Credit System Insurance Corporation was established. This insurance corporation requires that Farm Credit Banks to pay .0015 percent on accrual loans and .0025 non-accrual loans to the fund.

What is the current status of this fund? What oversight actions have been taken to manage this fund?

Mr. STEELE. The inaugural meeting of the Farm Credit System Insurance Corporation Board was held on February 27, 1990. No premiums have been collected. Funds from the old Farm Credit Revolving Fund were transferred to the Insurance Corporation in January 1989 and have been invested in Government securities. Interest earnings up to February 1, 1990, were $11,718,681.75. On that date, the fund had a balance of $271,517,397.75.

AGRICULTURAL CREDIT ACT

Mrs. SMITH. Thank you very much. Now, Mr. Thor, Congress has considered a number of pieces of financial bail out legislation such as the S&L Loan Program and the Agricultural Credit Act.

Would you briefly describe your opinion on the success of the Agricultural Credit Act? Has it achieved or is it achieving the goals that Congress hoped it would achieve when it was passed?

Mr. THOR. As we look at the Credit Act of 1987, which was amending the 1981 Act and the 1985 and 1986 Acts, I would have to say that it is largely a success.

You can take, for example, a bank like the Bank of Omaha, which received up to $110 million worth of assistance. That bank used it to restructure not only the way it did business, but also its liabilities.

As a result of that investment, we think the bank could save around $140 million in expenses over the next few years. As a result, both its loan business, as well as its credit administration, asset and liability management, and income has been substantially enhanced.

Therefore, I would have to say that the 1987 Act is working. As I testified, though, it is not complete. We still have a number of concerns and issues ahead of us that will have to be dealt with by both the Assistance Board and the Farm Credit Administration.

SPOKANE BANK

Mrs. SMITH. Now, I appreciate that answer. You know, there are quite a few people who are questioning the viability of the Spokane Bank at the present time.

Some are suggesting that it will need assistance from the Assistance Board. I was delighted to note that you were asking for a $22,000 decrease, and I thought that my staff made a typo when they said decrease, but I guess that is correct.

If you do have to help out the Spokane Bank, do you think that you asked for enough money to adequately address the problem?

Mr. THOR. Again, I believe the principal thing that concerns us is the increasing expenses for a System that has shrunk significantly over the last four or five years. Looking at a case like Spokane that used to be over a $5 billion bank, today it's under $3 billion.

Our Chairman, Secretary Yeutter, asked us to visit Spokane, which we did recently, to look at some of the issues, and we have asked the Spokane Bank where they stand.

As you know, they are not required at this time to seek assistance, but they are eligible, and we have notified the bank that they are eligible at this time, but they have not chosen so far to submit a request.

If they do submit a request, which we have been told is coming in a short time, they will have to deal with a number of problems, including not only the shrinking of their assets, but the fact that they maintained the highest debt cost in the system.

They have seen short term credit drop almost 80 percent. I personally think that the Assistance Board has enough staff and can call upon the appropriate people both from our Board and others to get that problem dealt with in a reasonable time frame.

BUDGET REQUEST

Mrs. SMITH. I am pleased in knowing that the Assistance Board has requested a FY91 funding level of $2.184 million, a $22,000 decrease from FY90 funding of $2.206 million.

As I told you earlier, I am pleasantly surprised by this decrease. However, I would like for you to explain to the committee the reason for this request. How did you arrive at a decrease in your funding request for FY91 compared to FY90?

Mr. THOR. During the first two years of the Assistance Board, we incurred many of the extraordinary costs of establishing an organization. Over time, we have accumulated what we think are the necessary tools, both personnel and materials, to accomplish our statutory mandate. With these start-up costs behind us, we have re-evaluated our administrative budget requirements. Consequently, we anticipate spending less than our Congressionally-set expense limitation during fiscal year 1990. For fiscal year 1991, we again anticipate the need for less than the FY 1990 limitation.

We feel this budget adequately reflects our operating costs at the current program level. It also includes amounts to accommodate any costs which may be associated with assistance to additional, System institutions independent auditing, or special projects.

ASSISTANCE BOARD AND OMAHA

Mrs. SMITH. In September of 1988, the Farm Credit Bank of Omaha was certified to receive $110 million in assistance from the Assistance Board. At that time, no one would question the financial difficulty facing that farm credit district.

Mr. Thor, would you update the subcommittee on the financial progress the Omaha Bank has made since receiving this assistance? Does the Omaha Bank continue to make significant progress?

Mr. THOR. Since receiving assistance, the Farm Credit Bank of Omaha has made strong progress in its recovery. Improvements have been made in all areas of operations. Accrual loan volume has stabilized. Nonaccrual loans and acquired properties have declined significantly. Credit administration and asset/liability management programs have been strengthened.

In 1989, the first full year of operations after assistance, the bank exceeded its budgeted goals in most areas. The bank is generating positive net earnings and net interest income. Net interest income for 1989 was nearly double the amount earned for 1988. Operating expenses have been reduced and the bank continues to seek additional ways to achieve efficiencies in its operations. The bank has met the FCA's interim minimum capital standard and is very close to meeting the permanent standard.

Mrs. SMITH. Thank you very much.

I have no further questions, Mr. Chairman.

FCA AUTHORITY

Mr. WHITTEN. Other than auditing, what authority do you have? I understand that, under the 1987 Act, your discretion and operations in approval of interest rates and things like that were divorced from your organization.

What have you got left except regulatory action, which is just auditing these operations? Do you have any influence or any authority to control those lending groups whom you audit?

Mr. STEELE. Mr. Chairman, we do not manage the banks. The Farm Credit Administration does have a responsibility in its due diligence of oversight to look at, through examination, and furnish to the bank boards and the Chief Executive Officer our evaluation to give them a tool for determining how they should proceed for a safe and sound bank and an efficient, effective one.

So it's indirect. We do not manage.

Mr. WHITTEN. You don't have the authority to do anything about it?

Mr. STEELE. In setting interest rates? No.

Mr. WHITTEN. You just have the privilege of telling them about it, if you wish to? You're not required to even advise them.

Mr. STEELE. Mr. Chairman, through examination we have a responsibility to advise them if, in fact, they're in violation of the

Safe and Sound Rules, but we don't have a privilege or a responsibility to tell them if their interest rates are correct.

Mr. WHITTEN. Mr. Natcher?

Mr. NATCHER. No questions, Mr. Chairman.

Mr. WHITTEN. Mr. Akaka?

Mr. AKAKA. Thank you very much, Mr. Chairman.

FORECLOSURES

Mr. Steele, I have heard time and again the Chairman's litany on foreclosures, and he has the years and experience to speak with authority.

From your recent experience with foreclosures within the institution of the Credit System, has the instance of foreclosures declined from the troubled years of the mid-1980s?

Mr. STEELE. Mr. Akaka, yes, sir. They have declined measurably.

Mr. AKAKA. Where are the hot spots where you experience the most problems today?

Mr. STEELE. The geographic areas that have been notable for the greatest problems are through the grain areas and also where the land prices escalated the greatest, the Middle West, the West, then the South, and then the East, in that order.

DISTRICT CONSOLIDATION

Mr. AKAKA. I understand that you have a program of consolidation in a number of districts. Can you tell me the status and the basis upon which you're consolidating those districts?

Mr. STEELE. Well, the consolidation has been to this date, limited to the merger of the Federal Land Banks and Federal Intermediate Credit Banks in 11 districts. There has also been considerable merger and consolidation activity among associations. Eleven of the 13 Banks for Cooperatives have also merged. But there has been no consolidation of districts.

HIGH RISK LOANS

Mr. AKAKA. What percentage of loans within the Farm Credit System are in the high risk category? How does the number of high risk loans compare to previous years?

Mr. STEELE. The number of high risk loans are measurably less, but if it would be agreeable with you, I should like to furnish the answer to the first question for the record to be more specific.

Mr. AKAKA. Will you please do that? I'd appreciate that.

Mr. STEELE. Thank you.

[The information follows:]

The following chart provides information pertaining to nonperforming (high risk) loans as a percentage of total gross loans outstanding of the Farm Credit System institutions for the past 5 years.

FARM CREDIT SYSTEM NONPERFORMING LOANS AS PERCENT OF TOTAL LOANS

	1989	1988	1987	1986	1985
Nonaccrual loans	5.03	6.47	9.97	12.13	7.63
Restructured loans	4.67	3.85	2.52	.62	.47
Other high risk loans	4.29	5.03	8.14	9.86	5.77
Total nonperforming loans	13.99	15.35	20.63	22.61	13.86

Mr. **Akaka**. Do you find that Farm Credit institutions are getting an increased share of high risk loans, or has the ratio remained stable in recent years?

Mr. **Steele**. From the statistics that I have seen, the Farm Credit System has been receiving a lower percentage of high risk loans as the agricultural community has improved greatly its financial viability. So the percentage of high risk loans is a good bit less.

LOAN PERFORMANCE

Mr. **Akaka**. Would you please give me the amount of high risk loans carried by the Farm Credit System institutions over the past few years?

Mr. **Steele**. I will provide, for the record, a chart which shows the information pertaining to nonperforming (high risk) loans of the Farm Credit System institutions for the past 5 years.

[The information follows:]

FARM CREDIT SYSTEM NONPERFORMING LOANS—5-YEAR TREND

[In millions of dollars]

	1989	1988	1987	1986	1985
Nonaccrual loans	2,553	3,329	5,234	7,066	5,323
Restructured loans	2,366	1,980	1,321	363	327
Other high risk loans	2,174	2,586	4,273	5,742	4,028
Total nonperforming loans	7,093	7,985	10,828	13,171	9,578

Mr. **Akaka**. Thank you.

PROBLEMS OF THE 80'S

I have a question for Mr. Thor. I'm glad to read your statement that the financial assistance mechanism of the Agricultural Credit Act of 1987 is working.

Also, part of that, of course, is credit to your organization as an Assistance Board. You also point out that there was trouble in the early 1980s, and you also point out that you have improved the credit service by 225,000 farmers and ranchers in 15 states, which is good news.

My question to you is how does this compare to prior to the early 1980 problems that came at that time?

Mr. **Thor**. Mr. Congressman, the basic problems that beset the Farm Credit System in the early 1980s were really three- or fourfold.

One of them was the fact that the Farm Credit System was ill prepared to deal with both higher and very unstable interest rates.

Take credit services to farmers, for example. In your fine state, as you know, there are a number of rural needs that need to be met in a very timely fashion.

Frankly, the credit administration and systems were not in place in either the banks nor in the various institutions that serve the Farm Credit System, including our predecessor, the Capital Corp., to deal with those issues.

Today, with everybody working, including Congress and yourself who helped create the Act and helped get it signed, we have been able to reinstill a number of basic principles.

In my testimony, I cover those basic principles for stronger service and dealing with the farmers and ranchers. We do hold farmer and rancher meetings around the country in various States, but have not yet in yours, though that might be a good idea.

We have been working only with those institutions that technically can apply for assistance, i.e., those that have more liabilities than assets.

So the bottom line is we've been focusing them on their back-to-basics, and they have been focusing themselves on better service to farmers and ranchers.

Mr. **Akaka**. Thank you very much.

Thank you, Mr. Chairman.

Mr. **Whitten**. Mr. Skeen? Oh, excuse me, Mr. Myers. I didn't see you.

Mr. **Skeen**. I defer to my ranking member here.

Mr. **Myers**. Thank you, Mr. Chairman.

Well, frankly, I don't know enough about what you're doing to ask any questions, but I will make a comment. Back when I worked for a living, I was a country banker and I never made a bad loan.

A lot of them went bad, and a lot of them didn't collect. But since that time I have learned it's a lot easier to make a loan than collect it.

Anybody can make a loan, but sometimes it was difficult to collect. I have certainly experienced that through my life.

My dad used to tell me that well, anybody can run a bank in good times. It just takes a lot of help to run a bank. After all, you're not just running banks. You're helping manage the system that provides the credit.

I also remember that I knew a few farmers with whom I tried to do business who thought they could go in and borrow money if they were making a profit.

That's the only way they measured their profit. As long as their credit was good, they didn't worry about whether they were making money or not. They just had to keep their head above water.

So, it's a tough job that you have in trying to provide a tool, and credit is certainly a tool, just the same as a cultivator or a tractor or a combine. It's a tool.

I think too often we look upon it not as a tool, but as a substitute for profit, and that it isn't. I realize that there are some farmers who are still having difficult times. But, I think we're beginning to see the light at the end of the tunnel and I think we all have to work together to get there.

I'm not going to tell you how to run your job. I can't even run this end very well, so I'm not about to tell you how to run yours.

But hang in there and try to keep as many farmers alive as you can. Thank you for the job you're doing.

Mr. **Whitten**. Mr. Skeen?

Mr. **Skeen**. Thank you, Mr. Chairman.

That was a great statement, John.

Those of us who have been engaged in agriculture for a number of years understand the importance of credit, and we also understand the importance of what has happened to us prior to this time.

This is a rebuilding era, and I want to tell you that I don't envy the job that you have, but I do admire the fact that you've accepted it and are doing well with it.

Mr. Steele, I want to ask you a question. With the reductions that you've proposed, and I understand what you're doing, you've had reductions in personnel, you have a hiring freeze on, but I think you've kept your personnel intact, but you're not taking on any new ones——

Mr. **Steele**. Mr. Skeen, we lost some people before we put the increase in salary, but we've not lost enough to prevent us from carrying out our mission.

We're in a strong position in the area of examination and enforcement.

Mr. **Skeen**. But you've raised your salary levels?

Mr. **Steele**. Yes, sir.

Mr. **Skeen**. You had to stay competitive?

Mr. **Steele**. That's very true, in order to keep our people.

Mr. **Skeen**. With the reductions that you had in training and purchases of equipment and so forth, do you think you've got enough to get your job done?

INCREASING WORKLOAD

Mr. **Steele**. For fiscal year 1990, we're down to raw bones. We're down to no fat. We're down to limiting some things that we should do, but we can and do carry out our mission.

But when the new budget comes out, it's essential that it be approved in order for us to rebuild and carry on some training and some other vital areas for us to proceed into the future to carry out our additional load.

The additional load has to do with Farmer Mac, our additional load has to do with the added responsibility of the Farm Credit System Insurance Corporation, and the like. So, yes, the load is heavier, and we will need the money to do it.

Mr. **Skeen**. Well, let me ask you this question. It may be auspicious, but at this point do you see any benefits to the program as you've initiated it?

Is it paying off any or is it going the right direction? What are the indicators showing?

Mr. **Steele**. For the Farm Credit Administration?

Mr. **Skeen**. Yes, sir.

Mr. STEELE. The indicators are very specific in that the reports of the examination to the lending institutions are doing the job they are intended to do.

That makes me feel real good, particularly when the reports give the boards the kind of tool that will help them perform their professional responsibilities to a higher degree.

It also helps the Government in its responsibility to the investor, as funds are invested from Wall Street, that provides the money Farm Credit System institutions lend.

MERGERS

Mr. SKEEN. Well, I think it all adds up to one thing, and that's restoring confidence, and I'll talk to Mr. Thor about that in just a moment.

I want to cover one more area with you before I leave the Farm Credit Administration, and that is the numerous PCAs across the country that are wanting to combine with other banks.

I understand the problem, mainly it's self-preservation of capital, because requirements are to help out the ailing PCAs, and it's not very attractive to some of them, even though they made the agreement in the beginning.

Now, there seems to be an interest in being transient, and they're saying let's find a better place to operate. Give me your opinion of that.

I know that three of these are in New Mexico and are seeking to move from the Wichita Bank and go to the Texas Bank.

Just give me your general opinion of that.

Mr. STEELE. First of all, it's very delicate.

Mr. SKEEN. Oh, I understand that.

Mr. STEELE. If an association were to leave the current assigned area and go to an adjacent bank, leaving that first bank, Bank A, then, would have the opportunity of performing like services; therefore, there could be internal competition within the——

Mr. SKEEN. Well, this leads to something called overchartering, so moving you does not necessarily reserve you that space or that area, because all you've done is vacate a space. Am I correct?

Mr. STEELE. That's correct.

Mr. SKEEN. Go ahead.

Mr. STEELE. I'm saying this would be a new experience for the system. It has not been involved in this before, and it's very sensible to this country boy that that's going to bring lots of heartache.

Mr. SKEEN. Well, it appears to me that when this happens, and should it be approved, you're opening that area to another free agent initiation. Someone could charter another bank in the area.

Mr. STEELE. Or the territory that's being vacated could be served by another association affiliated with the bank.

Mr. SKEEN. So they become a whole different entity. Is that correct?

Mr. STEELE. Right. So it's one of the things that the Farm Credit Administration is in the process of doing and needs to do. If we had more people, we could do these things on a priority basis to a greater degree than we have in the past and get the regulations formed to take care of instances like this, but it's a very difficult situation.

Mr. SKEEN. There are no obstacles, really, other than seeking permission to transfer. Or what are the obstacles?

Mr. STEELE. Well, the obstacles are to create the kind of regulations that would cover some of the bases that aren't covered currently.

Again, by overlapping, this is a real problem. Again, this creates competition between system institutions.

Mr. SKEEN. Well, it doesn't really get down to the heart of the matter of how do you resuscitate those that are not sound systems? Does that completely leave that as another question?

Mr. STEELE. It is another question. For those that aren't sound systems, then we could look to the other part of the formula, and that is for two banks to merge.

Mr. SKEEN. Oh, I see. So you're narrowing the base constantly.

Mr. STEELE. You would be narrowing the base in that you would be narrowing the delivery system, yes, which could be more efficient.

Mr. SKEEN. I thank you for that, because, as you say, it's a very touchy situation, and it's not easy to deal with, and it's been in transition for some time.

NONEXCLUSIVE CHARTERS

Let me ask a hypothetical question. If the New Mexico PCAs were allowed to transfer to Texas, would you allow the Wichita bank to charter another PCA in the state of New Mexico? And if Wichita was allowed to charter another PCA in New Mexico, would you then allow the Texas bank to charter a new land bank?

Mr. STEELE. The FCA Board's policy on granting nonexclusive charters to associations was adopted November 22, 1988. The Board noted that when an association transfers its affiliation from one Farm Credit Bank to another under section 433 of the 1987 Act, the predecessor Farm Credit Bank retains that territory within its charter. Accordingly, it is possible that the FCA will receive a request to charter a new association or expand the charter of an existing association to enable it to serve borrowers within that territory who wish to obtain credit from an association affiliated with the predecessor Farm Credit Bank. In either case, the FCA will consider the best interests of the borrowers and the likelihood of business success in its decision on such a charter request.

I cannot respond to your last question because the FCA Board policy does not address this matter; also, no such request has been received from an association that would be affiliated with the Farm Credit Bank of Texas. However, should such a request be submitted, the FCA Board would, I believe, again consider the relevant factors involved, which are the best interests of the borrowers and the likelihood of business success in the New Mexico territory.

TRANSFER OF NEW MEXICO PCA'S

Mr. SKEEN. Do you see any major obstacles that would prevent the PCAs in New Mexico from transferring? Could you briefly explain what is happening at this point with the New Mexico requests to transfer?

Mr. **Steele**. The FCA issued conditional preliminary approvals to the PCA of Eastern New Mexico on April 28, 1989, and to the PCA of Southern New Mexico and the Albuquerque PCA on May 1, 1989. Basically, the conditions require the associations to execute certain required changes to their respective stockholder disclosures and the agreement and plan of reassignment. The associations were directed to return the revised proposals to FCA so that it could be determined if the conditions had been met. The Albuquerque PCA submitted a revised proposal February 8, 1990; the others have yet to do so. It appears that two issues have yet to be resolved—the retirement of the association's investment in the Farm Credit Bank of Wichita, which is not in accordance with FCA regulations on Board policy, and the association's claim to an exclusive charter following its affiliation with the Farm Credit Bank of Texas. The FCA believes these remaining problems can be overcome and will seek resolution by the principal parties involved.

RELATIONSHIP OF BOND RATES AND INTEREST RATES

Mr. **Skeen**. What effect have bond rates had on interest rates?

Mr. **Steele**. Bond rates represent the wholesale cost of money and are the largest component of interest rates paid by farmers. Changes in bond rates have a direct effect on the interest rates charged to Farm Credit borrowers. Higher bond rates will be reflected in higher interest rates, all other factors being held constant. Of course, changes in other factors (such as operating costs, provision for loan losses, amount of nonaccruing loans, and the need to build up capital) could also affect interest rates charged. The spread, the difference between the average rate on earnings assets and the average rate on interest-bearing debt, must be sufficient to cover all these costs. The competition from other lenders for good borrowers will affect the interest rates charged, so the effect of higher bond rates on interest rates charged may not always be realized immediately, and the interest rate spread may vary over time.

Between the fourth quarters of 1988 and 1989, the average rate on Farm Credit bonds outstanding rose from 9.72 to 9.92 percent, while the average rate on accrual loans (FCB and PCA loans) rose from 10.75 to 11.06 percent.

RESTORING INVESTOR CONFIDENCE

Mr. **Skeen**. For restoring confidence, we'll go back to Mr. Thor. I was particularly interested in your statements on the agricultural bonds and revitalization of that interest, because that's a good indicator of whether or not we have investor interest in these bonds. I would think that also indicates that maybe we're on the upswing, and it's about time.

Give me an overall assessment of what you think the investor interest is at this time, both from the agricultural bond area and also from private sources?

Mr. **Thor**. Very good. Congressman, generally the interests of the investor in Farm Credit System securities as they continue to seek quality investments around the world has indeed been a very positive one.

You may remember that back during 1986 and 1987, the spread on, for example, a six-month Farm Credit issue was up over 150 basis points on certain days.

The bond issue closing here March 1st, will be in the 20 to 30 basis point range only, depending upon how you count it.

That fact alone is worth several hundred million dollars to these institutions and to the farmers that ultimately will be the recipients of the loans and are owners of the System.

So right now I think that is a very good indicator of the return to viability. We do have a ways to go, but it suggests that investors from around the country and around the world are looking favorably at the general financial health of the Farm Credit System.

Additionally, Standard and Poors and Moody's and others that have rated the Farm Credit System have given it the highest quality, AAA.

That is a very positive sign. It also means that investors are willing to invest in American agriculture over many other things, including S&L kinds of securities and things like that which have a lesser grade today in terms of wider spreads.

So I am indeed watching it closely. It's something that can change very quickly, but it is a very positive indication of the success of the Act and how it is working for the farmers.

Mr. **Skeen**. Can you quantify the international investment outside the United States investment in agricultural bonds?

Mr. **Thor**. Well, again, we have an international financial community today that invests, whether it's in U.S. Treasury or Farm Credit System securities. In individual issues for example, it's pretty much impossible to tell when a bond is issued exactly where it's going to go and into which investment pool.

Generally, most securities today run anywhere from 35 to 25 percent. I would have to go back and check and get back to you if there are some specifics. I'd have to ask the Funding Corporation.

Mr. **Skeen**. Well, in your estimation, is there a great deal of interest from international sources?

Mr. **Thor**. I think there's a great deal of interest from all areas, including international.

Mr. **Skeen**. But we don't know how much.

Mr. **Thor**. We don't know how much, but one of the key things is that this is a very basic and a very important part of the American economy.

As the Chairman has repeatedly pointed out to us, as goes American agriculture, so goes the rest of the economy. I think it's important that the international investment community is giving us a much stronger vote of confidence than they were two years ago.

Mr. **Skeen**. That was the reason I asked the question, the irony of the fact that we're talking about what we've lost in international markets, yet what we're gaining in international investors, and I don't know what the offsets are and how they play in the issue.

INTEREST RATE CONCERNS

Please tell me what is the impact on higher interest rates such as we're experiencing now in the international securities markets on the Farm Credit securities?

Mr. THOR. Well, again, maybe the Chairman would like to answer that question.

Mr. SKEEN. Interest rates across the board.

Mr. THOR. Or I would be happy to just say briefly that I'm not in a position to answer that question. I'd have to gather the information for the record, but with the increasingly global nature of today's financial markets, Farm Credit System Securities must compete with other foreign and domestic investment vehicles for a finite amount of investment capital. In the past few weeks, international interest rates have risen and put upward pressure on System and U.S. Treasury Securities' rates.

Mr. SKEEN. I'd appreciate that, because what has hurt the farm economy and the Farm Credit System has been highly cyclical increases in interest rates that the agricultural community has absolutely no control over.

That's what started this roller coaster ride. If we hadn't had 20 percent interest rates a few years ago, we could have borrowed ourselves along and stayed pretty current.

But when they shot up to around 20 percent and everybody had to get around the usury laws and had to reorganize every little farming group in the country into a corporation, those are the kinds of highs and lows and the rapid cycling of those interest rates that are really bothersome.

Let me ask you this. I know, Mr. Thor, that you've asked for reductions or you've reduced your request on appropriations. Are you going to be able to take care of your responsibilities under this budget?

Mr. THOR. I am.

Mr. SKEEN. You are. I admire you both very much. I think you're doing a good job, and I will be watching with great interest to see how it works out. Thank you both.

Thank you, Mr. Chairman.

Mr. WHITTEN. May I say that the point I've been trying to make, and I may not have made it clear, is that it looks to me like the 1987 Act just left you as an auditing firm.

Now there are a lot of issues, such as the way we're handling agriculture, exports and imports, that I differ on with the President.

But they seem to have taken any input away from you folks by reason of your position. Personally, I'm sure they listen to your recommendations, but as I understand it you are an auditing firm. You just check the books.

Mr STEELE. Mr. Chairman?

Mr WHITTEN. I'm telling you how I understand it so that you can explain differently if it goes beyond that.

Mr. STEELE. I should like to explain beyond that, Mr. Chairman.

Mr. WHITTEN. Go ahead.

FCA RESPONSIBILITIES

Mr. STEELE. It's far beyond that, because the Congress has given the Farm Credit Administration the necessary teeth to carry out its responsibility in case there are violations of the lending institutions.

Those teeth are such that it's far more——

Mr. Whitten. A violation of what?

Mr. Steele. A violation of safety and soundness———

Mr. Whitten. Which to me is just an auditor.

Mr. Steele. I'm sorry?

Mr. Whitten. All you do is pass judgment on whether it's safe or sound?

Mr. Steele. We do, through examination, to see if that lending institution is, in fact, following the basic——

Mr. Whitten. If they counted their money right, and the total is added up right, then there's nothing to say. I mean, you have no authority to advise these lending institutions in their operations.

Mr. Steele. Asset quality is key. Internal audit is key. The quality of the loan is key. All of these are exceedingly important, and all of this falls within the province of the examinations.

Also, we can place a lending institution in the position of their having to correct that condition or the Farm Credit Administration then can take the next steps to reach the maximum to closing down a bank or changing the Board of Directors.

Mr. Whitten. I know you are new, and I wish you the very best of everything.

Mr. Thor has been with the Assistance Board for some time. How many complaints have you made against the institutions that have gone beyond their operating plan?

I may be wrong, but I'd just like to know how much of that you've been doing, and I ask this of Mr. Thor because he's been there longer.

Mr. Thor. Mr. Chairman, we operate a bit differently from the Farm Credit Administration. We, with each of the institutions, signed an assistance agreement by which they provide to us a business and operating plan. We work with them and sit down with their Boards of Directors and senior management on almost a monthly basis.

We review problems that may come up, we review the kinds of things that they're doing to not only ensure that they're safe and sound, but that they're making strides toward their long term capital goals and their long term profitability.

Mr. Whitten. If you differ with them, whom do you report to?

Mr. Thor. I then turn around and summarize that for my Board, which consists of Secretary Yeutter, Secretary Brady and Mr. Will Erwin.

FINANCIAL ASSISTANCE TO FARM CREDIT INSTITUTIONS

Mr. Whitten. Mr. Thor, at last year's hearing you testified that the Assistance Board had received and acted upon 16 assistance requests from Farm Credit Banks, Production Credit Associations, and the Federal Land Bank Associations. Were there any new requests during fiscal year 1989 or the early part of fiscal year 1990? For the record, please list all Farm Credit institutions that have received financial assistance from the Board and how much was provided.

Mr. Thor. The Assistance Board received no new requests for assistance during fiscal year 1989 or during early fiscal year 1990.

The Farm Credit Bank of Spokane has informed us that it intends to submit a request for financial assistance.

The Farm Credit Banks of Louisville, Omaha, and St. Paul have been certified as eligible to receive financial assistance. The banks received approximately $90 million, $107 million, and $133 million, respectively. Also, the Federal Land Bank of Jackson in Receivership was certified as eligible to receive $45 million of financial assistance to retire maturing debt and protected borrower stock.

Mr. WHITTEN. The Assistance Board was given five years to accomplish its statutory purpose of providing assistance and helping the Farm Credit System through fiscal crisis. Because of a stronger rural economy than faced the Nation four years ago, we assume that the need to provide financial assistance is significantly lessened and that the majority of the efforts of the Assistance Board now will be in monitoring those System entities that received financial assistance. Can you please bring us up to date on the financial health of those System entities that received Assistance Board finances?

Mr. THOR. All of the certified institutions have made progress since receiving assistance. Non-earning assets have fallen. In 1987, the St. Paul, Louisville, and Omaha banks, in total, had $1.8 billion of nonaccrual loans and $358.3 million of acquired property, for a total of approximately $2.2 billion of non-earning assets. By the end of 1989, the three banks had reduced these non-earning assets to a combined total of $622 million, a reduction of 72 percent. Each bank is predicting further reductions in this cateogry for 1990.

Accrual loan volume in the certified institutions, and the System as a whole, has stabilized. In 1985, the total combined accrual loan volume of the three now-certified banks was approximately $19 billion. By the end of 1988, the total had fallen to $12.0 billion. By the end of 1989, accrual loan volume in the certified institutions had stabilized at $12 billion.

Income quality has improved. While the assisted institutions' combined 1989 net income of $164.6 million was down from last year's $232.7 million, the quality has improved dramatically. Last year's total was inflated by $456.9 million of loan loss reserve reversals. During 1989, the certified institutions reduced this reversal to only $49.9 million.

Net interest income in the assisted banks has increased in 1989 to $193.7 million from the 1988 level of $110.5 million. Similarly, 1988's operating loss of $40.1 million has turned to operating income of $62.1 million in 1989. This improvement is due, in part, to a reduction in operating expense from the 1988 figure of $150.6 million to $131.6 million in 1989.

Capitalization levels have improved. Each certified institution has met the interim regulatory capital adequacy standards and is making progress toward permanent regulatory capital adequacy standards. In addition, all certified banks have a mechanism in place to set aside earnings to repay the financial assistance received.

SPECIAL COMMITTEE ON DISTRICT CONSOLIDATION

Mr. WHITTEN. Mr. Thor, at last year's hearing the Special Committee on District Consolidation had not yet completed its report, and you were projecting cost savings of between $50 million and $80 million to the System from consolidation. Please summarize for us the contents of the report and what actions have been taken to date on the report and its recommendations.

Mr. THOR. The mission of the Special Committee, as defined by Congress, was to develop a proposal to consolidate the Farm Credit Banks—FCBs—into no less than six financially viable FCBs through interdistrict mergers. The Report notes that Booz-Allen & Hamilton, Inc., was retained by the Special Committee to assist the Committee's analytical work. Based on the merger partners suggested by Booz-Allen analysis, the Special Committee investigated the ability of the identified potential partners to merge. The Special Committee's Report found three conclusions.

The first was that savings could be achieved through the reduction in the number of FCBs. Booz-Allen suggested that the merger of certain FCBs could generate an annual saving of $55–80 million. Considerable discussion has raised questions regarding this conclusion. Secondly, "[D]ue to ongoing significant structural change within the System outside the purview of the Committee, financial issues stemming from the involvement of the Assistance Board in four districts, and significant operational differences between the System's banks, [and] despite all reasonable efforts to investigate the matter, it cannot be determined, from available information, within the time provided by the Congress, whether any merger or mergers of FCBs would yield a system of no less than six financially viable FCBs." And finally, a period of structural stability would benefit the System and permit the investigation of additional consolidation alternatives.

In light of these conclusions, the Special Committee adopted and included as part of its Report a resolution recommending that System service organizations encourage, assist and monitor further consideration and development of proposals to consolidate FCBs and/or proposals for shared-services among FCBs. In addition, the resolution included in the report endorses consolidation of System service organizations.

Given the findings by the consultants and committee, the Assistance Board urges System institutions to pursue merger and consolidation opportunities. As has been the case with previous requests for assistance, we will consider the merger possibilities for any System institution seeking certification.

NATIONAL SPECIAL ASSET COUNCIL

Mr. WHITTEN. For the record, please provide copies of the last four quarterly reports on the activities and findings of the National Special Asset Council.

Mr. THOR. I will submit the reports for the record. Three sentences from the National Special Asset Council second quarter report for 1989 have been redacted because they summarize information in FCA examination reports covered by a confidentiality agreement between the FCA and the Assistance Board. FCA has not authorized the release of this information. Two of these three sentences are repeated in the first quarter report for 1989 and, therefore, those two sentences have also been redacted from that report for the same reason. Requests for release of the redacted information should be submitted to FCA pursuant to 12 CFR 602.205.

[The information follows:]

APPENDIX A

NATIONAL SPECIAL ASSET COUNCIL

Suite 702
1301 Pennsylvania Avenue, NW
Washington, DC 20004

(202) 737-9255

SUBJECT: First Quarter (1989) Status Report

TO: Eric P. Thor
President and CEO

FROM: Ken Auberger
Executive Secretary

General

A written summary of National Special Asset Council (Council) activities was presented to the Assistance Board at its March 13, 1989, meeting. I also made a brief oral presentation on the activities of the respective Special Asset Groups (SAG). Following the meeting, Mr. Erwin and I met with Deputy Secretary Peter Myers, at his request, for a more detailed discussion of Farm Credit bank restructuring activities.

A quarterly meeting of the Council was held on April 12, 1989. The third member position remains vacant. Mr. Erwin announced that his family's financial relationship with the Farm Credit Bank of Louisville no longer exists, thus eliminating any possible appearance of personal impropriety. Accordingly, he will no longer recuse himself from discussions or actions having to do with activities of the Louisville SAG.

Special Asset Group Activity

Louisville - The SAG at Louisville has been operating for eight months with no serious problems evident.

Number of restructure denials and other loans reviewed as of March 31:	397
Agree with bank's decision:	397

The bank completed the review of all loans in nonaccrual status at the date of certification, within 9 months, as required by the Agricultural Credit Act of 1987. SAG officials submit to the Council monthly, a Nonaccrual Loans Status Report, which shows the results of the bank's review. The following information was reported at March 31.

Restructured	768	28%
Returned to accrual status	333	12%
Paid off (includes acq. prop.)	283	10%
Accelerated/foreclosed	359	13%
In bankruptcy or other litigation	137	5%
To be resolved	901	32%
Total	2,781	100%

Under their program, SAG officials conduct field reviews to test confirm the bank's servicing of nonaccrual loans. These field reviews will continue in the months ahead and will cover both loans in nonaccrual status as of the date of certification and loans transferred to nonaccrual status since that date.

[redacted]

Omaha - The Omaha SAG has been operating satisfactorily for five months.

Number of restructure denials and other loans reviewed as of February 28:	113
Agree with bank's decision:	113

Like Louisville, SAG officials submit to the Council monthly, a Nonaccrual Loans Status Report. The bank has until May 12, 1989 (9 months from the date of certification), to complete the review of loans that were in nonaccrual status at the date of certification. A breakdown of the bank's review of these nonaccruals at February 28, follows.

Restructured	434	20%
Returned to accrual status	188	9%
Paid off (includes acq. prop.)	632	30%
In bankruptcy or other litigation	252	12%
To be resolved	611	29%
Total	2,117	100%

The bank's determinations on nonaccrual loans are monitored by the Regional Quality Control staff.

St. Paul - The St. Paul SAG has been operating for four months. A few start-up problems appear to have been resolved.

Number of restructure denials reviewed as of February 28:	284
Agree with bank's decision:	284

Operations of the St. Paul SAG differ from operations of the Louisville and Omaha SAGs in one respect. At St. Paul, denials of borrower restructure proposals are reviewed by the SAG at the bank level, and SAG officials also travel to the field offices to review all other nonaccrual loan determinations of the bank.

At February 28, the St. Paul SAG had reviewed the bank's determination on 268 of the 2,431 loans that were in nonaccrual status at the date of certification. SAG officials expect to complete their review by July 6 (thus meeting the statutory requirement to review such loans within 9 months of the date of certification). I am working with SAG officials to obtain a breakdown by category similar to the breakdowns furnished by Louisville and Omaha.

Jackson FLB in Receivership

On February 16, Kathleen Mullarkey and I met with Receiver officials in Jackson. The purpose of the trip was to make it clear to the Receiver that the Assistance Board will insist that they establish a SAG function that meets statutory requirements, and make monthly activity reports to the Council. At the meeting, Receiver officials informed us that they had created a two-person SAG, and they outlined plans for its operation. Subsequently, the Receiver submitted revisions to their Borrower Rights Manual incorporating the SAG function and its operations.

Number of restructure denials reviewed as of March 31:	63
Agree with Receiver's decision:	63

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Except for a small number of rural home loans, all of the restructure denials were farm loans secured by real estate mortgages.

cc: Mr. Erwin
Mr. Olmes

NATIONAL SPECIAL ASSET COUNCIL

Suite 702
1301 Pennsylvania Avenue, NW
Washington, DC 20004

(202) 737-9255

25 JUL 1989

Subject: Quarterly Report on
Activities of Special Asset Groups

To: James E. Olmes
Jeanne Kling

From: Ken Auberger
Executive Secretary

Transmitted herewith, is the report for the second quarter of 1989, covering activities of the district Special Asset Groups at Louisville, Jackson, Omaha, and St. Paul.

If you approve the report, please so indicate by signing the cover page of the report.

cc: Eric P. Thor
Christine Pembroke

NATIONAL SPECIAL ASSET COUNCIL

Suite 702
1301 Pennsylvania Avenue, NW
Washington, DC 20004

(202) 737-9255

NATIONAL SPECIAL ASSET COUNCIL

REPORT FOR SECOND QUARTER 1989

Prepared by:

Kenneth J. Auberger
Kenneth J. Auberger
Executive Secretary

Approved by:

James E. Olmes
James E. Olmes
Chairman

Date: 8/1/89

Background

The following background comments are for the benefit of the new members of the National Special Asset Council.

As required by the Agricultural Credit Act of 1987, all loan restructure denials by banks receiving financial assistance are referred to and reviewed by the respective district Special Asset Groups.

Pursuant to agreements with the Council, the Special Asset Groups submit monthly activity reports to the Council. Accompanying these monthly reports is summary documentation on each loan reviewed by the Special Asset Group, indicating the reason(s) for the bank's denial of restructuring, and the determination of the Special Asset Group to either concur with the denial or recommend a restructure plan. The documentation submitted consists of forms approved by the Council and brief loan summaries prepared by the loan officers or service centers.

As Executive Secretary, I review the documentation on every loan and, based on that documentation, formulate an opinion on the reasonableness of the determinations reached by the Special Asset Groups and the overall quality of their work.

The Council does not review bank restructure denials files in detail, relying instead on reports by Farm Credit Administration examiners who make a sample review of restructure denials during the course of their annual examinations of the banks.

Farm Credit Bank of Louisville

- The Special Asset Group has been operational for 11 months, and as of May 31, had reviewed a total of 463 cases with total indebtedness of $ 84.2 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 125 for $ 35.7 million involved restructure denials, and the Special Asset Group agreed with the bank's decision in every case.

- For calendar year 1988, the bank restructured a total of 1,185 loans, in the amount of $ 261.9 million. For the first four months of 1989, a total of 289 long-term loans have been restructured, in the amount of $ 60.2 million.

[redacted]

[redacted]

More currently, FCA has informally advised us of two borrower rights problems in the Louisville district: failure to give right of first refusal notice to borrowers when the method of sale of property changes (this has been corrected), and failure to promptly notify borrowers of their rights when their loans become distressed.

Farm Credit Bank of Omaha

- o The Special Asset Group has been in operation for 7 months, and as of May 31, had reviewed a total of 168 cases with legal liability of $ 25.8 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 65 cases for $ 14.4 million involved restructure denials, and the Special Asset Group agreed with the bank's decision in every case.
- o At May 31, the bank was carrying a total of 3,225 formally restructured loans, in the total amount of $ 451.3 million. We have communicated to bank officials our need for more detailed information on the number and dollar amount of restructured loans.

Farm Credit Bank of St. Paul

- o The Special Asset Group has been in operation for 6 months, and as of May 31, had reviewed and upheld a total of 67 bank restructure denials with principal balances of $ 12.8 million.
- o For calendar year 1988, the bank restructured a total of 1,710 loans in the booked amount of $ 438.7 million. For the period January 1 to May 31, 1989, the bank restructured a total of 222 loans for a booked amount of $ 33.3 million. As of May 31, the bank had 8,243 restructured loans totaling $ 1,153.6 billion.

Jackson FLB in Receivership

- The Special Asset Group, established in December of 1988, did not in our view meet statutory requirements, and at our insistence the Receiver made certain modifications in February of 1989. Nevertheless, we continue to be dissatisfied with facets of the operation. Specifically, we have told Receiver officials that Special Asset Group officials need to more fully explain the reasons for restructure denials.
- As of May 31, the Special Asset Group had reviewed and upheld a total 93 Receiver restructure denials.
- The Jackson Receiver has been requested to start providing the Council periodic data on restructured loans. However, on June 19, the Receiver, in a statement before the Senate Agriculture Credit Subcommittee, stated that the Receiver has completed 120 individual restructures involving debt with a book value of $ 25.7 million, and 144 reamortizations involving debt with a book value of $ 13.4 million.

Overview

The following general comments are applicable to all of the district Special Asset Group activities.

- To-date, the Special Asset Groups have agreed with the banks' restructure denial decisions in every case. No Special Asset Group has rejected a bank restructure denial and proposed a restructure plan of its own. Several cases, however, were returned to the bank for additional information.

  Based on my review of the documentation submitted to the Council by the Special Asset Groups, I found no basis to disagree with the decisions reached. [redacted]

  This outcome is probably due to the fact that, because a restructured loan contributes to profit and thus is in the banks' best interest, restructure plans would be denied only when they do not result in the least cost to the bank or they do not provide reasonable assurance as to the viability of the borrowers' continuing operation. Contributing factors would include the effectiveness of bank restructuring policies and procedures and staff training programs.

- The principal reasons why specific restructure plans are denied are (a) the cost of restructure exceeded the cost of foreclosure, (b) the borrowers' plan did not apply all income over and above necessary living and operating expenses to the payment of primary debts, and (c) the inability of the borrower to establish a viable operation even after some sort of restructuring. In some cases, restructuring could not be pursued because arrangements could not be worked out with junior lien holders.

  In a large number of distressed loan cases, the borrowers choose not to submit restructure plans or they are unwilling to provide the information needed to formulate a plan. In these cases, the bank has no alternative but to proceed with foreclosure.

- It is important to keep in mind that not all restructure denials result in foreclosure. Some borrowers file under one of the bankruptcy plans, others make payments to bring their loan account current, or the bank defers action, for various reasons, such as waiting to see if the borrower can make arrangements with the Farmers Home Administration.

- In some cases, in order to clear title or cooperate with other lien holders, the borrower and the bank will agree to a foreclosure action.

- The vast majority of the restructure denials involve farm loans secured by real estate mortgages. Only a small number are rural home loans to non-farmers. The Special Asset Groups at Louisville and Omaha do review rural home loans before foreclosure even though the borrower rights provisions of the 1987 statute do not apply to such loans. The St. Paul Special Asset Group does not review rural home loans.

NATIONAL SPECIAL ASSET COUNCIL

Suite 702
1301 Pennsylvania Avenue, NW
Washington, DC 20004

(202) 737-9255

Subject: Quarterly Report on
Activities of Special Asset Groups

To: James E. Olmes
Jeanne Kling

From: Ken Auberger
Executive Secretary

Transmitted herewith is the report for the third quarter of 1989, covering activities of the district Special Asset Groups at Louisville, Omaha, and St. Paul; and the Special Asset Group for the Federal Land Bank of Jackson in Receivership.

If you approve the report, please so indicate by signing the cover page of the report.

cc: Eric P. Thor
Christine Pembroke

NATIONAL SPECIAL ASSET COUNCIL

REPORT FOR THE THIRD QUARTER 1989

Prepared by:

Kenneth J. Auberger
Executive Secretary

Approved by:

James E. Olmes
Chairman

Date:

Background

This brief background information is repeated at the beginning of each quarterly report for the benefit of the reader.

As required by the Agricultural Credit Act of 1987, all loan restructure denials by banks receiving financial assistance are referred to and reviewed by the respective district Special Asset Groups.

Pursuant to agreements with the National Special Asset Council (Council), the Special Asset Groups submit monthly activity reports to the Council. Accompanying these monthly reports is summary documentation on each loan reviewed by the Special Asset Group, indicating the reason(s) for the bank's denial of restructuring, and the determination of the Special Asset Group to either concur with the denial or recommend a restructure plan. The documentation submitted consists of forms approved by the Council and brief loan summaries prepared by the loan officers or service centers.

As Executive Secretary, I review the documentation on every loan and, based on the documentation, formulate an opinion on the appropriateness of the determinations reached by the Special Asset Groups and the overall quality of their work.

The Council does not review bank restructure denial files in detail, relying instead on reports by Farm Credit Administration examiners who make a sample review of restructure denials during the course of their annual examinations of the banks.

Restructure Denials

From certification through September 30, 1989, the Louisville, Omaha, and St. Paul banks made determinations not to restructure a total of 368 loans, with total legal liability balances of $83.7 million.

Information on each of the three banks follows:

	Louisville	Omaha	St. Paul
No. of restructure denials reviewed by Special Asset Groups	153	76	139
Denials as a percent of total nonaccrual loans reviewed by the bank	.04	.025	.04
Amount of legal liability (millions)	$41.5	$16.4	$25.8

Farm Credit Bank of Louisville

- From its creation, upon certification of the bank on May 12, 1988, through September 30, 1989, the Special Asset Group had reviewed a total of 549 cases with total indebtedness of $93.5 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 153 for $41.5 million involved determinations not to restructure. In the other cases, the borrowers chose not to apply for restructure or they refused to provide the bank the financial and other information needed for the development of a restructure plan.
- For the first nine months of 1989, a total of 626 long-term loans have been restructured, in the amount of $133.5 million. Restructures after April 1 represent the determinations of the district associations that purchased the mortgage loan portfolio from the bank on March 31.
- The Special Asset Group will continue to review restructure denials associated with the mortgage loans sold to the associations on March 31. Restructure denials associated with new loans made by the associations after March 31 will not be subject to review by the Special Asset Group.

Farm Credit Bank of Omaha

- From inception, through September 30, 1989, the Special Asset Group had reviewed a total of 236 cases with total indebtedness of $33.4 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 76 for $16 4 million involved restructure denials. In the other cases, the borrowers chose not to apply for restructure or they refused to provide the bank the financial and other information needed for the development of a restructure plan.
- At September 30, the bank's loan portfolio included 3,310 formally restructured loans, in the total amount of $457.8 million.

Farm Credit Bank of St. Paul

- The Special Asset Group, from date of certification through September 30, 1989, had reviewed a total of 139 restructure denials with principal balances of $25.8 million.

- At September 30, the bank's loan portfolio included 8,432 restructured loans totaling $1.18 billion. For the period January 1 through September 30, 1989, the bank has restructured a total of 378 loans totaling $56.7 million.

Jackson FLB in Receivership

- As of August 31, 1989, the Special Asset Group had reviewed a total of 109 determinations of the Receiver not to restructure the loans, in the amount of $30.5 million.
- As of September 30, the Receiver reports a total of 162 voluntary restructures for $39.4 million; and 145 reamortizations totaling $13.7 million.

Overview

The following analysis generally tracks comments included in the draft 1989 annual report for the Council.

- The vast majority of the restructure denials involve farm loans secured by real estate mortgages. Only a small number are rural home loans to non-farmers.
- The principal reasons why some borrower restructure plans are denied remain the same as covered in the second quarter report.
    - the cost of restructure was greater than the cost of foreclosure.
    - the borrowers' restructure plan did not apply all income over and above necessary living expenses to the payment of primary debt.
    - the borrower did not have the financial capacity and management skills to protect the collateral from diversion, dissipation, or deterioration.
    - the borrower was unable to establish a viable operation even with some sort of restructuring.
    - the borrower had the capacity to repay the loan under its present terms.
- In a very large number of cases, the distressed borrowers chose not to submit a restructure plan or they were unwilling to provide the bank with the financial information needed to formulate a plan.

4

- In many cases, the bank and the borrower eventually agree on a restructure plan other than the plan that was rejected. These are the cases where:
    - the realization that the bank intents to proceed with foreclosure forces the borrower into serious negotiation.
    - the borrower is able to restructure his/her Farmers Home Administration debt.
    - the bank and the borrower agree to a "friendly foreclosure", thus eliminating the position of an uncooperative second lien holder.
- None of the bank restructure denials were overturned by the Special Asset Groups. Bank officials attribute this result to the process prescribed by the Act that the banks are required to follow in reviewing nonaccrual loans for possible restructuring.

Conclusion

The Special Asset Groups are reviewing all restructure denials and are functioning in an appropriate and business-like manner.

NATIONAL SPECIAL ASSET COUNCIL

Suite 702
1301 Pennsylvania Avenue, NW
Washington, DC 20004

(202) 737-9255

FEB 5 1990

Subject: Quarterly Report on
Activities of Special Asset Groups

To: James E. Olmes
Jeanne Kling

From: Ken Auberger
Executive Secretary

Transmitted herewith is the report for the Fourth Quarter of 1989, covering activities of the district Special Asset Groups at Louisville, Omaha, and St. Paul; and the Special Asset Group for the Federal Land Bank of Jackson in Receivership.

If you approve the report, please so indicate by signing the cover page of the report.

cc: Eric P. Thor
Christine Pembroke

NATIONAL SPECIAL ASSET COUNCIL

REPORT FOR THE FOURTH QUARTER 1989

Prepared by:

Kenneth J. Auberger

Kenneth J. Auberger
Executive Secretary

Approved by:

James E Olmes

James E. Olmes
Chairman

Date: 2/5/90

Background

This brief background information is repeated at the beginning of each quarterly report for the benefit of the reader.

As required by the Agricultural Credit Act of 1987, all loan restructuring denials by banks receiving financial assistance are referred to and reviewed by the respective district Special Asset Groups.

Pursuant to agreements with the National Special Asset Council (Council), the Special Asset Groups submit monthly activity reports to the Council. Accompanying these monthly reports is summary documentation on each loan reviewed by the Special Asset Group, indicating the reason(s) for the bank's denial of restructuring, and the determination of the Special Asset Group to either concur with the denial or recommend a restructuring plan. The documentation submitted consists of forms approved by the Council and brief loan summaries prepared by the loan officers or service centers.

As Executive Secretary, I review the documentation on every loan and, based on the documentation, formulate an opinion on the appropriateness of the determinations reached by the Special Asset Groups and the overall quality of their work.

The Council does not review bank restructuring denial files in detail, relying instead on reports by Farm Credit Administration examiners who make a sample review of restructuring denials during the course of their annual examinations of the banks.

Restructuring Denials

For the quarter ended December 31, 1989, the Louisville, Omaha, and St. Paul banks made determinations not to restructure a total of 36 loans, with outstanding balances totaling $6.6 million.

The activity for the quarter increased the total number of determinations not to restructure from certification through December 31, 1989, to 404, with outstanding balances of $90.1 million.

Information on each of the three banks follows:

	Louisville	Omaha	St. Paul
Quarter ended 12/31/89:			
No. of determinations reviewed by the Special Asset Groups	9	6	21
Outstanding balances (millions)	$2.5	$0.4	$3.7
Total through 12/31/89:			
No. of determinations reviewed by the Special Asset Groups	162	82	160
Outstanding balances	$44.5	$16.8	$29.5
Determinations as a percent of total nonaccrual loans reviewed by the bank	4.6	5.1	2.5

Farm Credit Bank of Louisville

- From certification of the bank on May 12, 1988, through December 31, 1989, the Special Asset Group reviewed a total of 593 cases with outstanding balances of $100.8 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 162 for $44.5 million involved determinations not to restructure. In the other cases, the borrowers chose not to apply for restructure or they refused to provide the bank the financial and other information needed for the development of a restructure plan.
- For the year ended December 31, 1989, the bank restructured a total of 766 long-term loans with balances of $161.7 million. Restructures after April 1, 1989, represent the determinations of the district associations which purchased the mortgage loan portfolio from the bank on March 31.
- The Special Asset group will review future determinations not to restructure any of the mortgage loans sold to the associations on March 31. Determinations not to restructure new mortgage loans made by the associations after March 31 will not be subject to review by the Special Asset Group, but the borrowers will be entitled to all of the borrower rights provisions of the Act.

Farm Credit Bank of Omaha

- From certification through December 31, 1989, the Special Asset Group reviewed a total of 264 cases with outstanding balances of $36.6 million, where the bank had made a determination to proceed with foreclosure. Of these totals, 82 for $16.8 million involved determinations not to restructure. In the other cases, the borrowers chose not to apply for restructure or they refused to provide the bank the financial and other information needed for the development of a restructure plan.

- For the year 1989, the bank restructured a total of 310 loans totaling $56.7 million. At December 31, the bank's loan portfolio included 3,233 formally restructured loans, with balances of $439.3 million.

Farm Credit Bank of St. Paul

- From certification through December 31, 1989, the Special Asset Group reviewed a total of 160 cases with outstanding balances of $29.5 million, where the bank had made a determination not to restructure. Other cases, such as those where the borrower chooses not to apply for foreclosure or refuses to cooperate, are also reviewed by the Special Asset Group but the bank does not keep separate statistics on these cases.

- For the calendar year 1989, the bank restructured a total of 519 loans totaling $76.6 million. At December 31, 1989, the bank's loan portfolio included 8,543 restructured loans totaling $1.2 billion.

Jackson FLB in Receivership

- As of November 30, 1989 (activity report for December not received), the Special Asset Group had reviewed a total of 141 determinations made by the Receiver not to restructure for $38.8 million.

- Through December 31, the Receiver reported a total of 181 voluntary restructures for $50.7 million; and 149 reamortizations totaling $13.8 million.

Overview

- The number of cases reviewed by the Louisville, Omaha, and St. Paul Special Asset Groups, where the banks make determinations not to restructure, is decreasing. The banks completed their reviews of the loans that were in nonaccrual status at the dates of certification several months ago, and are current with their reviews of loans placed in nonaccrual status subsequent to the dates of certification. Put another way, the banks have pretty much worked through their backlogs. The general agricultural economy will have a direct bearing on the future number of bank distressed loans.

  However, there are several hundred nonaccrual loans that, while reviewed, have not been resolved. The banks will eventually make determinations not to restructure some of these loans and they be subject to review by the Special Asset Groups. The other unresolved loans will be restructured, returned to accrual status, or paid off.

- The majority of the loans reviewed by the Special Asset Groups are long-term loans secured by real estate mortgages. A small number are rural home loans to non-farmers.

- The reasons for the banks' determinations not to restructure remain constant.

  - the cost of restructure was greater than the cost of foreclosure.

  - the borrower's restructure plan did not apply all income over and above necessary living expenses to the payment of primary debt.

  - The borrower did not have the financial capacity and management skills to protect the collateral from diversion, dissipation, or deterioration.

  - the borrower was unable to establish a viable operation even with some sort of restructuring.

  - the borrower had the capacity to repay the loan under its present terms.

- As stated above, in a very large number of cases, the borrowers chose not to submit a restructure plan or they were unwilling to provide the bank the financial information needed to formulate a plan.

- It is the policy of all three certified banks to negotiate with a borrower right up to the time of actual foreclosure. Consequently, in many cases, the bank and the borrower do reach agreement on a restructure plan other than the plan that was originally rejected by the bank and reviewed by the Special Asset Group.

  For the most part, these are the cases where:

  - the realization that the bank intends to proceed with foreclosure forces the borrower into more serious negotiation.
  - the borrower is able to arrange for full or partial Farmers Home Administration financing.
  - something is worked out with second lien holders.

- None of the bank determinations not to restructure have been overturned by the Special Asset Groups. Bank officials attribute this result to the process prescribed by the Act that the banks are required to follow in reviewing nonaccrual loans for possible restructuring.

- As this report is prepared, the Council has under consideration a borrower interview program. The objective of the program would be to further ensure that the process of reviewing borrower restructuring plans is sufficient and is meeting the requirements of the Act.

Conclusion

The Special Asset Groups are reviewing all determinations of the banks not to restructure and the banks are functioning in an appropriate and business-like manner.

Mr. Whitten. What expenses were incurred by the Assistance Board in relation to its work with the Asset Council's activities during fiscal year 1989 and what are your projections for 1990 and 1991?

Mr. Thor. During fiscal year 1989 the Assistance Board spent $22,023 to support the NSAC. For 1990 and 1991, we budgeted $55,700 to $60,800 respectively.

FINANCIAL ASSISTANCE CORPORATION

Mr. Whitten. When the Financial Assistance Corporation and Board was originally authorized, as much as $4.5 billion in obligations was estimated as necessary to assist the Farm Credit System. Those estimates appear to be falling significantly short. Again this year, would you provide a table on the latest estimates for the bond sales and interest rates, by quarter, and a comparison chart to your original estimates? Please provide your projections through fiscal year 1991.

Mr. Thor. While it is still too early to determine how much assistance may eventually be necessary, the Assistance Board does not anticipate the entire $4 billion authorization will be used.

The Assistance Board has never projected the amount or timing of Financial Assistance Corporation bond issues. I will provide for the record, for appropriations purposes only, what the Administration has projected as part of its fiscal year 1991 budget.

Current administration estimate (fiscal year 1991 budget)

	Millions
Bonds issued:	
Fiscal year:	
1990	$635
1991	$450

Projected FAC interest rates by quarter: (Projected Treasury rate plus 40 basis points)

	Interest rate
Fiscal year 1990:	
Quarter 1	8.40
Quarter 2	8.30
Quarter 3	8.20
Quarter 4	8.00
Fiscal year 1991:	
Quarter 1	7.70
Quarter 2	7.50
Quarter 3	7.30
Quarter 4	7.00

Original administration estimate (fiscal year 1988 OMB mid-year review)

	Millions
Bonds issued:	
Fiscal year 1988:	
Quarter 1	$0
Quarter 2	$1,079
Quarter 3	$300
Quarter 4	$150
Fiscal year 1989:	
Quarter 1	$150
Quarter 2	$73
Quarter 3	$146
Quarter 4	$73
Fiscal year 1990:	
Quarter 1	$73
Quarter 2	$85
Quarter 3	$170

Quarter 4	$85
Total	$2.384

Projected FAC interest rates: (Projected Treasury rate plus 25 basis points)

	Interest rate
Fiscal year 1988:	
Quarter 1	8.50
Quarter 2	8.10
Quarter 3	8.00
Quarter 4	7.80
Fiscal year 1989:	
Quarter 1	7.70
Quarter 2	7.60
Quarter 3	7.40
Quarter 4	7.30
Fiscal year 1990:	
Quarter 1	7.10
Quarter 2	7.00
Quarter 3	6.80
Quarter 4	6.70

NOTE.—Amounts reflected above apply only to that portion of FAC bonds for which the U.S. Treasury is responsible for partial payment of interest.

Mr. WHITTEN. Please also provide a chart that shows OMB's original estimates for interest rates and how they compare with actual rates.

Mr. THOR. I will provide a table for the record.

[The information follows:]

OMB INTEREST RATE ASSUMPTIONS VERSUS ACTUAL INTEREST RATES

	Fiscal year 1989 budget	Actual
1988:		
Quarter 1	9.1	8.97
Quarter 2	8.4	8.40
Quarter 3	8.1	8.90
Quarter 4	7.9	9.10
1989:		
Quarter 1	7.7	9.00
Quarter 2	7.6	9.20
Quarter 3	7.5	8.80
Quarter 4	7.3	8.10
1990:		
Quarter 1	7.2	8.00
Quarter 2	7.0	
Quarter 3	6.9	
Quarter 4	6.7	

Note.—All interest rates are for Treasury bonds longer than 6-year maturity.

Mr. WHITTEN. For the record please provide a table of the Financial Assistance Corporation expenditures through December 31, 1989.

Mr. THOR. The Financial Assistance Corporation has given us its year-end 1989 financial statements which I will submit for the record.

[The information follows:]

APPENDIX B

Farm Credit System
Financial Assistance Corporation

90 William Street
New York, New York 10038
212/908 9400

March 5, 1990

Mr. Eric P. Thor
Farm Credit System Assistance Board
1301 Pennsylvania Avenue, N.W.
Suite 702
Washington, D.C. 20004

Dear Eric,

As per your request, I am enclosing the following Financial Assistance Corporation schedules:

(1) Summary Schedule of Bonds Issued
(2) Summary of Cash Flows Associated With Various Uses of Proceeds
(3) Financial statements as of 2/28/90

If you should have any questions, please contact me at (212) 908-9422.

Sincerely,

Dan

Daniel M. Bienz
Vice President - Disclosure and Financial Reporting

enclosures

3.6.90
1167

Farm Credit System
Financial Assistance Corporation

90 William Street
New York, New York 10038
212/908 9400

Farm Credit System
Financial Assistance Corporation
Summary Schedule of Bonds Issued

Provide Capital Assistance	$370,552,670.00
Capital Preservation cash outs	414,186,433.00
Assistance Board expenses	2,876,000.00
Retirement of eligible protected borrower stock	23,951,253.00
Debt issuance costs:	6,481,035.50
Concessions	
Discount	
Interest on promissory notes	563,497.98
Prefunding	28,389,110.52
Total	$847,000,000.00

9 3/8% Bond due 7/21/2003	$450,000,000.00
9.45% bond due 11/21/2003	240,000,000.00
9 1/2% bond due 4/16/2004	157,000,000.00
Total	$847,000,000.00

Contoller's Department
12/31/89

Farm Credit System
Financial Assistance Corporation

90 William Street
New York, New York 10038
212 908 9400

Farm Credit System Financial Assistance Corporation Summary of Cash Flows Associated With Various Uses of Proceeds

ses of roceeds:	Fund Capital Preservation Accruals	Financial Assistance to Individual Institutions	Facilitate Mandatory Mergers, Pay Assistance Board Expenses, Redeem Stock in Liquidating Institutions	Concessions, Discounts, Interest on Promissory Notes
ay Interest irst 5 Yrs:	Sys Banks 100%	Treasury 100%	Treasury 100%	Treasury 100%
y Interest econd 5 Yrs:	Sys Banks 100%	Treasury 50% Sys Inst 50%	Treasury 50% Sys Inst 50%	Treasury 50% Sys Inst 50%
ay Interest hird 5 Yrs:	Sys Banks 100%	System Inst 100%	System Inst 100%	System Inst 100%
epay Principal t Maturity Call:	System Banks	Assisted Inst 100%	System Inst	System Inst
epay Interest unded by reasury	NA	On a fair and equitable basis established by FCA but only after all FAC debt obligations have been repaid		

System institutions may pay more than 50% if System unallocated retained earnings exceeds a specified percentage.

The 1987 Act specifically provides that, prior to maturity, the debt used to fund third quarter 1986 Capital Preservation cash outs shall not be considered a liability of any Bank for financial reporting purposes.

While the technical amendments specifically provide repayment sources for funds used to facilitate mandatory mergers, to pay Assistance Board expenses, and to redeem stock in liquidating institutions, it is silent on concessions, discounts, and interest on promissory notes. It is a logical extension, however, that System institutions should repay them: the only item to be paid by Banks, Capital Preservation cash outs, was originally a Bank obligation, and debt used to fund assistance to an institution will be repaid through the retirement of preferred stock.

inancial Assistance Corporation

Farm Credit System
Financial Assistance Corporation
Statement of Condition at February 28, 1990

Assets:	
Restricted assets:	
Trust Fund:	
Investment securities comprised of U.S. Treasury Bills-at cost which approximates market value	$188,296,314
Assistance Fund:	
Investment securities comprised of U.S. Treasury Bills-at cost which approximates market value	32,414,012
Receivables:	
U.S. Treasury-interest reimbursement	8,176,819
System Banks-interest reimbursement	8,182,188
Reimbursements of other expenses receivable-System Banks	29,388
Miscellaneous receivables-System institutions	113,338,479
Investments in preferred stock:	
Preferred stock (1)	370,552,670
Allowance for loss	(40,000,000)
Total preferred stock	330,552,670
Capital Preservation receivables-System Banks (2)	417,174,035
Prepaid concession expenses	2,175,270
Prepaid insurance	13,084
Investment-D&O Reciprocal	40,000
Total assets	$1,100,392,259
Liabilities:	
Payable to Funding Corporation	$82,371
Payable to stockholders	142,120,440
Payable to receiving banks-Capital Preservation (2)	1,171,567
Bonds payable	847,000,000
Accrued interest payable-bonds	16,359,007
Promissory notes payable (3)	80,195,777
Accrued interest payable-promissory notes (3)	882,291
Unamortized discount-bonds	(3,720,192)
Deferred credit (4)	5,895,462
Payable to Insurance Fund	10,405,536
Total liabilities	1,100,392,259
Capital:	
Capital stock	37,506,664
Accumulated deficit	(37,506,664)
Total capital	0
Total liabilities and capital	$1,100,392,259

Farm Credit System
Financial Assistance Corporation
Statement of Income
For the two months ended February 28, 1990

	Current period	Year to date
Income:		
Interest income-Trust Fund	$1,130,603	$2,345,002
Interest income-Assistance Fund	193,034	404,470
Reimbursements:		
Interest expense	6,684,557	13,369,114
Interest on promissory notes	442,671	882,291
Assistance Board operating expenses	156,000	199,100
Other expenses	25,158	27,817
Total income	8,632,023	17,227,794
Expenses:		
Interest expense-bonds payable	6,684,557	13,369,114
Interest expense-promissory notes	442,671	882,291
Assistance Board operating expenses	156,000	199,100
Other expenses:		
Legal fees	5,354	5,354
Trust Fund-Litigation	2,171	2,171
Advertising	0	0
Publication production cost	0	0
Accountants' fees	0	0
Insurance	2,633	5,267
Audit fees	15,000	15,000
Federal Reserve services	0	25
Total other expenses	25,158	27,817
Interest expense-Shareholder payment	0	0
Provision for loss on investment in preferred stock	0	0
Provision for return of unused funds in Assistance Fund and Trust Fund to the Insurance Fund	1,323,637	2,749,472
Total expenses	8,632,023	17,227,794
Net loss	$0	$0

Notes to Financial Statements

(1) Represents investment in preferred stock of the following:

FLB of Jackson	$ 40,000,000
FCB of Louisville	90,000,000
FCB of Omaha	107,156,670
FCB of St. Paul	133,396,000
	$370,552,670

(2) On January 11, 1988, $415 million of contributing Bank Capital Preservation accruals relating to the third quarter of 1986 were assumed by the Financial Assistance Corporation. Approximately $414 million was paid in 1988 and 1989 and funded by the issuance of U.S. Treasury-guaranteed debt in accordance with provisions of the 1987 Agricultural Act and procedures established by the Financial Assistance Corporation Board of Directors.

Since the April 18, 1989 debt issuance was used solely for the purpose of funding Capital Preservation cash outs, the repayment obligation for the discount related to that issuance ($1,816,035.50) has been treated in the same manner as the repayment obligation for the cash outs.

To date, cash outs have been made to the following Banks:

	April 18, 1989	July 22, 1988
FCB Louisville	$39,722,433.00	$ 9,248,000.00
FLB Jackson	49,043,386.33	24,356,613.67
FCB St. Louis	18,363,000.00	00.00
FCB St. Paul	00.00	179,283,000.00
FCB Omaha	32,145,526.00	45,554,474.00
FCB Wichita	16,470,000.00	00.00

The remaining payable is to FCB Louisville for $1,171,567.

(3) The promissory notes outstanding are all payable to FLB of Jackson. Promissory notes nos. 9-5, 9-6, 9-7 which were due to mature on 1/03/90 and promissory note no. 9-8 which was due to mature on 2/21/90 have been extended until 5/03/90 and therefore, have incurred interest expense.

(4) Represents the unamortized discount and concessions on debt issued.

Farm Credit System
Financial Assistance Corporation
Expense Budget Review
Two Months Ended February 28, 1990

Annual 1990 Budget	Item	1989 Actual	1990 Prorated Budget	1990 Actual	Variance Over/(Under) 1989 Actual	Variance Over/(Under) 1990 Prorated Budget	
						Amount	Percent
$5,000	Accountant's fees	$0	$0	$0	$0	$0	--
37,500	Audit fees	0	15,000	15,000	15,000	0	0.0%
75,000	Legal fees	0	12,500	5,354	5,354	(7,146)	-57.2%
350,000	Trust Fund-Litigation	0	58,332	2,171	2,171	(56,161)	-96.3%
44,000	Insurance	10,774	7,332	5,267	(5,507)	(2,065)	-28.2%
8,000	Publication production costs	0	0	0	0	0	--
2,000	Federal Reserve services	0	332	25	25	(307)	-92.5%
30,600	Advertising	0	0	0	0	0	--
$552,100	Total	$10,774	$93,496	$27,817	$17,043	($65,679)	-70.2%

Farm Credit System
Financial Assistance Corporation
Summary Schedule of Bonds Issued

Provide Capital Assistance	$370,552,670.00
Capital Preservation cash outs	414,186,433.00
Assistance Board expenses	3,075,100.00
Retirement of eligible protected borrower stock	23,956,814.00
Debt issuance costs: Concessions Discount	6,481,035.50
Interest on promissory notes	563,497.98
Prefunding	28,184,449.52
Total	$847,000,000.00

9 3/8% Bond due 7/21/2003	$450,000,000.00
9.45% bond due 11/21/2003	240,000,000.00
9 1/2% bond due 4/16/2004	157,000,000.00
Total	$847,000,000.00

Contoller's Department
2/28/90

FCS CAPITAL CORPORATION

Mr. Whitten. When the Assistance Board was originally created, there were a large number of lawsuits pending against the Capital Corporation, your predecessor. Please bring us up to date on the resolution of the remaining lawsuits, which at this time last year there were approximately 15 actions still in various stages.

Mr. Thor. As a result of the statutory transfer to the Assistance Board of the Capital Corporation's assets and liabilities, the Assistance Board, since its creation in January 1988, has become party to 48 lawsuits and one administrative proceeding filed against the Capital Corporation by System institutions and others. The Assistance Board, through the Department of Justice, has actively pursued various options in an effort to resolve these proceedings. Last April we reported to you that 15—14 lawsuits and one administrative proceeding—of these 49 actions were still pending. As of March 1, 1990, 6 of these lawsuits remain—2 of which are on appeal (in both cases, the Assistance Board's Motions to Dismiss the Complaint were granted) and 1 in which the Complaint has been filed but there has been no service on the Assistance Board.

FCSAB ADMINISTRATIVE BUDGET AND EXPENSES

Mr. Whitten. Please include for the record an object class table of your expenses for fiscal years 1989, 1990 and 1991.

Mr. Thor. I will provide a table for the record.

[The information follows:]

Object class		Actual fiscal year 1989 expenses	Projected fiscal year 1990 expenses	Fiscal year 1991 budget
11	Personnel compensation	$979,079	$1,176,000	$1,266,000
12	Personnel benefits	168,462	186,500	224,000
21	Travel	102,056	107,900	117,500
22	Transportation of things	1,162	2,200	2,400
22	Rent, comm., and utilities	174,328	186,000	203,000
24	Printing	3,777	7,000	8,600
25	Other services	106,315	188,700	322,800
26	Supplies and materials	24,453	30,300	33,400
31	Equipment	21,934	5,800	6,300
	Total	1,581,566	1,891,100	2,184,000
Congressional budget limitation		2,000,000	2,206,000	....

Mr. Whitten. Also provide an object class table for your activities related to the National Special Asset Council, the Special Committee on District Consolidation, appointed Board Members, and assistance monitoring.

Mr. Thor. I will also provide a table for the record.

[The information follows:]

Object class		Actual fiscal year 1989 expenses	Projected fiscal year 1990 expenses	Fiscal year 1991 budget
National Special Asset Council:				
21	Travel	$2,523	$7,400	$8,100
24	Printing	0	1,000	1,200
25	Other services	19,500	46,000	50,100

Object class	Actual fiscal year 1989 expenses	Projected fiscal year 1990 expenses	Fiscal year 1991 budget
26 Supplies and materials	0	1,200	1,400
Total	22,023	55,700	60,800
Special Committee on District Consolidation:			
21 Travel	7,405	0	0
25 Other services	73	0	0
Total	7,478	0	0
Appointed Board Member:			
11 Personnel compensation	42,467	46,000	50,000
12 Personnel benefits	8,896	8,800	9,500
21 Travel	20,932	19,200	20,400
25 Other services	88	100	100
26 Supplies and materials	130	0	0
Total	72,513	74,100	80,000

Mr. WHITTEN. Please provide for the record a table indicating the number of FTEs and the General Schedule grades of each.

Mr. THOR. I will provide that information for the record.

[The information follows:]

Farm Credit System Assistance Board full-time staff and GS-grade equivalents

	GS-grade equivalent
Executive Office:	
President and Chief Executive Officer	E–3
Executive Secretary	11
Advisor to the President and CEO	13
Vice President (vacant)	16
Secretary	9
Administration:	
Director of Administration	15
Deputy Director	12
Administrative Assistant	11
Bookkeeper/Financial Manager	10
Receptionist/Secretary	7
Finance and Analysis Division:	
Treasurer and Director of Finance and Analysis	15
Senior Analyst	14
Financial Analyst	14
Financial Analyst (vacant)	13
Secretary	8
Legal Division:	
General Counsel and Corporate Secretary	15
Deputy General Counsel	15
Assistant General Counsel	14
Secretary	9
Public Information and Legislative Affairs Staff:	
Director, Public Information and Legislative Affairs	15
Public Affairs Officer	10
Legislative Affairs Officer	12

FEDERAL LAND BANK OF JACKSON

Mr. WHITTEN. We know that the General Accounting Office issued a report in December 1989 entitled, "Farm Credit—Basis for Decision Not to Assist Jackson Federal Land Bank." This report was somewhat critical of the decision process used by the Assistance Board in making its final determinations on whether to provide assistance or not to the Jackson Federal Land Bank. Please provide the GAO recommendations and the Assistance Board responses to each.

Mr. **Thor**. The Assistance Board believes that the decision made by the Board of Directors, which at the time consisted of the former Secretaries of Agriculture and the Treasury, to recommend that the Farm Credit Administration place the Jackson Federal Land Bank into receivership was based on well-grounded and extensive financial analysis. Further, the decision was made only after the Assistance Board met with groups of farmers and ranchers regarding agricultural credit service by the Jackson Federal Land Bank. As history has shown, the decision was a good one for the Jackson farmers and ranchers. Since the bank was placed in receivership, six new federal land bank associations have been chartered, two each in the states of Alabama, Mississippi and Louisiana, to serve the entire district. The farmers and ranchers have received the full value for their eligible borrower stock, can once again receive long term agricultural credit and are receiving credit at better rates than the ailing Jackson Federal Land Bank could offer.

One GAO Recommendation was that, although future assistance requests may be unique (i.e., institutions may need assistance to resolve different types of financial problems), costs would be estimated on the basis of a complete and well-supported analysis. Therefore, they recommended that the Assistance Board's Board of Directors direct its officials to use an analysis that: includes all relevant costs for each option; provides that data used in the analysis and key assumptions, such as interest rates, be supported by current, generally accepted economic sources; and compares cost on a present value basis.

The Assistance Board agreed with the GAO's recommendations and, in fact, followed each of these recommendations in its analysis of the Jackson Federal Land Bank's request and in all other requests submitted to date by Farm Credit System institutions. Further, the analytical procedures used by the Assistance Board with respect to requests for financial assistance assure that each of these recommendations will be followed in future analyses.

In our opinion, inclusion of these recommendations in GAO's Report results from the fact that there is a difference between the GAO and the Assistance Board in approach, opinion and emphasis with respect to the analysis conducted by the Assistance Board.

GAO also recommended that to help avoid misunderstandings between affected parties in possible future requests, the Assistance Board's Board of Directors direct its officials to issue guidance detailing the requirements for requesting assistance and the Assistance Board's role in helping institutions request assistance.

Because of the unique and individual problems faced by Farm Credit System institutions, as demonstrated by the four institutions that have applied for financial assistance, the Assistance Board does not believe it would be useful to publish general guidelines relating to requests for financial assistance. However, in the future, upon receipt of a request for financial assistance, the Assistance Board will send a detailed letter to the applicant institution setting forth the type of information the Assistance Board needs to consider the request, given the nature of the problems of that institution.

Further, this initial communication will make clear that, while the Assistance Board will provide comments and feedback on the material received, it is the responsibility of the applicant institution to put together a detailed, well thought out and realistic business recovery plan and assistance package.

Mr. WHITTEN. One of the GAO recommendations indicates that the Assistance Board should, in the future, use an analysis that includes all relevant costs for each option; provides that data used in the analysis and key assumptions, such as interest rates, be supported by current generally accepted economic sources; and compares costs on a present-value basis. Your response says that you agree with the GAO recommendations and, in fact, you did that. Obviously, GAO would not have made that recommendation if it thought you had done all of those things. Can you please provide some details on this difference of opinion between GAO and the Assistance Board?

Mr. THOR. The recommendation that the Assistance Board use an analysis that includes all relevant costs for each option relates to the GAO's opinion that the Assistance Board failed to include, in its analysis of the cost of receivership, the expense that would be incurred to pay interest on the principal amount of funds made available to the receiver. The GAO maintains that the Assistance Board included this expense in its analysis of the assistance necessary to restore the bank to viability. Simply put, the GAO's conclusion confuses the cost necessary to provide financial assistance or to liquidate an institution with the cost of funding those costs.

The GAO's recommendation that data used in the Assistance Board's analysis and key assumptions, such as interest rates, be supported by current generally accepted economic sources involves GAO's disagreement that the interest rate source used by the Assistance Board was a current and generally accepted economic source. The Assistance Board used an 8% interest rate based on the President's Budget, as developed by the Office of Management and Budget—OMB. The OMB made official cost estimates for FAC bond issues for the Federal budget since funds must be appropriated to pay the interest expenses on FAC bonds for the first 5 years. The interest rate estimate established by OMB for FAC bond issuance for the third quarter of fiscal year 1988, the time period of the Assistance Board's decision, was 8%. The GAO believes that the Assistance Board should have used the prevailing yield for Treasury securities adjusted to a constant maturity of 15 years as shown in *The Wall Street Journal* on March 31, 1988, which was 9%.

With respect to the GAO recommended that the Assistance Board's analysis compare costs on a prevent value basis, a present value analysis was in fact made and presented to the Assistance Board directors on two occasions. We believe GAO's comment is based on the degree of emphasis GAO believes should be placed on the use of present value. In addition to present value, the Assistance Board's analysis also estimated costs on a cash and future value basis, emphasizing the cash basis for a number of reasons, including the operational structure of System institutions.

CLOSING REMARKS

Mr. **Whitten**. I don't know that I made this clear earlier, but we need all the help we can get in the way of the Farm Credit System and Administration, and we count on you folks.

Mr. **Steele**. Mr. Chairman, on page four of our submitted paper, it suggests that as of December 31, 1989, there were 72 institutions with the combined assets of over $53 billion operating under FCA enforcement documents.

These enforcement documents are of numerous natures, including cease and desist orders, and most of those cease and desist orders were on consent.

Mr. **Whitten**. I'm glad to have that information. We need all the help we can get in order to deal on a sound basis. Thank you for your appearance.

Mr. **Steele**. Thank you, Mr. Chairman.

Mr. **Thor**. Thank you.

Mr. **Whitten**. Mr. Watkins and Mr. Weber have some questions they would like answered for the record.

[The questions and responses follow:]

GUARANTEED LOANS

Mr. **Watkins**. In light of the Administration's proposal to shift more farm loans to guaranteed loans and to focus on lending to beginning farmers, what percent of the Farm Credit System loan portfolio is guaranteed FmHA loans?

Response. Farm Credit System institution loans guaranteed by the Farmers Home Administration (FmHA) represented only 0.76 percent of their loan volume outstanding at yearend 1989.

Mr. **Watkins**. Could you provide for the record the number of borrowers with guaranteed FmHA loans in each district?

Response. As of yearend 1989, the number of borrowers, along with their aggregate loan amount outstanding, with loans guaranteed by FmHA in each district is provided in the following table.

FmHA GUARANTEED LOANS BY FARM CREDIT DISTRICT

District	Number of borrowers	Loan amounts outstanding (in thousands)
Springfield	138	$940
Baltimore	406	40,192
Columbia	626	30,161
Louisville	464	25,162
Jackson	296	23,760
St. Louis	447	31,335
St. Paul	797	124,335
Omaha	525	47,057
Wichita	179	16,181
Texas	50	4,332
Western	115	24,214
Spokane	223	17,559
Total	4,266	385,228

YOUNG AND BEGINNING BORROWERS

Mr. **Watkins**. What percentage of your loan portfolio is beginning borrowers?

Response. The agency collects information annually on loans made to young and beginning farmers in each Farm Credit district. Young farmers are defined as borrowers who are under the age of 35; beginning farmers are defined as borrowers with less than 6 years' farming experience. Young and beginning farmers who were borrowers of the Farm Credit System institutions represented 22 percent of the number of borrowers and 13.3 percent of the volume of loans outstanding from Farm Credit institutions at December 31, 1989. This was an increase from 11.2 percent of number and 16.1 percent of loan volume at yearend 1988.

DECLINE IN BORROWING

Mr. **Watkins**. Has out-migration of borrowers from the FCS's stopped?

Response. During 1989, total loan volume for the System declined 1.4 percent, compared with 2 percent in 1988. The amount of migration has substantially decreased compared to the loan volume declines for the previous 3 years (1985 to 1987) that ranged from 10 to 16.5 percent.

RETURN OF BORROWERS

Mr. **Watkins**. Since the enactment of the 1987 credit act, how has the loan portfolio of the Farm Credit System improved in terms of numbers of new borrowers and the return of former borrowers?

Response. The banks and associations are not required to report this information to us. Therefore, we are unable to answer your question.

NEW AUTHORITY FOR BANKS

Mr. **Watkins**. Should additional authority be given to the FCS to participate in additional rural development activities, what changes would be necessary for the FCA?

Response. The primary purpose of Farm Credit institutions is to serve agricultural producers. Their authorized lending to rural utility cooperatives, to agricultural processing and marketing facilities, to marketing and supply cooperatives, and to rural homeowners provides rural development benefits.

Programs that would allow these institutions to participate in additional rural development activities would pose new challenges for them and the Farm Credit Administration. The opportunity for System institutions to diversify their portfolios and to participate with other commercial lenders and Government-sponsored enterprises such as Fannie Mae, Freddie Mac, Farmer Mac, and the Small Business Administration could smooth out some of the cyclical swings that System institutions experience as single-industry lenders. This would reduce safety and soundness concerns. However, a lack of expertise in these new business opportunities and in lending to local governmental units would likely increase credit and business risks, at least initially, and require the FCA to monitor and examine the institutions more closely.

The Farm Credit Administration is, of course, a financial regulator responsible for the safety and soundness of the institutions under its jurisdiction. Any changes in the lending authorities of these institutions will affect FCA primarily by necessitating changes in its operating regulations and examination activities, which will likely require additional budget and staffing levels.

RESTRUCTURING

Mr. **Watkins**. Since 1987, how many borrowers have been restructured and retained as borrowers of the Farm Credit System? What type of restructuring has occurred? How many borrowers have left the system since 1987 due to the inability to restructure? How many borrowers have left of their own accord?

Response. The 1987 Agricultural Credit Act implemented reporting requirements on Farm Credit institutions regarding the restructuring and disposition of all distressed loans. Information reported to FCA by System institutions for 1989 indicates that approximately 8,700 borrowers, with a total of $953 million in loans outstanding, received monetary concessions by having their loans restructured. This represented over 60 percent of the number and volume of distressed loans identified during the past year by all Farm Credit institutions. Nearly 3,000 distressed borrowers, totaling $495 million in loans, were reported as either having their loans foreclosed on or liquidated by other actions. This represented 20 percent of the number of loans identified as distressed during the year and 30 percent of the distressed loan volume. The remaining borrowers identified as having distressed loans during 1989 either paid their loans in full or they were not disposed of at yearend. System institutions do not provide information to the FCA specifically on the number of distressed borrowers that voluntarily left of their own accord.

INTEREST RATES

Mr. Watkins. What is the variation of interest rates among district banks in terms of interest buy downs?

Response. The Farm Credit Act Amendments of 1986 removed the FCA's authority to approve interest rates and interest rate programs of Farm Credit institutions, so the agency no longer centrally compiles information on any rates offered. The FCA is aware that various Farm Credit institutions participate in different interest rate buydown programs offered by Federal and state agencies. The FCA examination activities routinely include an evaluation of an institution's participation in such programs when it evaluates restructuring alternatives for distressed borrowers.

PRIVATE RIGHT OF ACTION

Mr. Watkins. Does the FCA keep a record and track the cases pending on private right of action?

Response. FCA tracks significant pending cases in which the issue of a private right of action has been raised, although no formal compilation has been created.

Mr. Watkins. How much has the FCA/FCS spent in legal fees in litigation in private right of action cases?

Response. While FCA has been a party in several cases where the issue of private right of action has arisen, FCA has not litigated that issue since it is only raised as a defense by a Farm Credit institution seeking to dismiss a plaintiff's cause of action. There has been an expenditure of legal fees by the FCA in tracking private right of action cases, but no specific dollar figures have been compiled.

Farm Credit institutions do not report the amounts of their legal fees expended on specific types of litigation, nor are they required to do so. As a result, FCA does not possess the information requested.

Mr. Watkins. What efforts are underway within FCA to ensure that borrower's rights are protected in light of split court decisions on private right of actions?

Response. The FCA's mandated responsibilities are not affected by recent court rulings regarding the right of private action on borrower rights cases. Rather, as a regulator, it is the FCA's role to examine for statutory or regulatory compliance with borrower rights provisions and, when violations are discovered, to direct appropriate corrective actions.

Each Farm Credit institution that is a direct lender is examined at least annually. An evaluation of borrower rights policies and procedures is included within the scope of examination in each of these examinations. The FCA examines the practices of these institutions to determine if they comply with established policy and FCA regulations. In addition to formal training for FCA examiners on borrower rights compliance, the FCA has issued various bookletters and bulletins to ensure that these examinations are both consistent and thorough.

The agency's Special Examination Division is responsible for reviewing and investigating specific borrower rights complaints lodged by institution borrowers. The FCA also performs special purpose examinations which, as a primary focus, may include borrower rights compliance.

Farm Credit institution boards and management are directed to correct borrower rights deficiencies noted during the examination process. And, the FCA's Office of Regulatory Enforcement directs necessary corrective actions through the use of various supervisory documents, including Cease and Desist Orders.

Mr. Watkins. How many credit review committee decisions have been reversed?

Response. For the year 1989, Farm Credit institutions reported a total of 211 loans made and/or restructured due to reconsiderations by System credit review committees (established under the Agricultural Credit Act of 1987) that reversed previous adverse credit decisions. These reversals represented approximately $11.1 million in loan volume.

Mr. Watkins. Are there internal plans for an appeal system?

Response. There are no plans for an appeal system.

ACQUIRED PROPERTY

Mr. Watkins. I am concerned about FCS land in inventory. How many farms have been repurchased by the previous owners versus new farmers?

Response. Call Report data do not include details on loans made to purchase farm real estate previously foreclosed on and acquired by Farm Credit institutions. Evaluations of individual loans performed by the agency during examinations would routinely review a portion of the loans made for acquiring such farm real estate, but these are not aggregated because they would not provide a comprehensive picture.

Mr. **Watkins**. How much land is in FCS inventory now?

Response. The following provides the acreage currently available in each district and total dollar value associated with the acreage.

MARKET VALUE—FARM REAL ESTATE OWNED BY FARM CREDIT DISTRICT

District	Acres	Value (in thousands)
Springfield	927	$893
Baltimore	3,964	2,195
Columbia	25,423	18,374
Louisville	17,763	10,135
Jackson	50,033	26,953
St. Louis	71,329	33,651
St. Paul	222,265	186,841
Omaha	121,202	30,477
Wichita	180,943	28,625
Texas	248,008	61,719
Western	49,854	49,865
Spokane	148,539	33,544
Total	1,141,250	483,252

EXAMINATION COSTS OF FEDERAL AGRICULTURAL MORTGAGE CORPORATION

Mr. **Weber**. Mr. Steele, it is my understanding that a portion of the 14% increase that you are requesting for your budget would go toward the work that you have done for Farmer Mac? Have you billed Farmer Mac for any of the services that you have provided them?

Response. Because of the startup delays of Farmer Mac, we have only just begun our work there. Farmer Mac will be billed when the FY 1990 work is completed. The amount is not known at this time.

LOAN RESTRUCTURING

Mr. **Weber**. Mr. Thor, would you please review for me how you feel the restructuring program that the St. Paul district has initiated is working?

Response. The St. Paul Farm Credit Bank began to aggressively restructure distressed loans in late 1986, a year before the Agricultural Credit Act of 1987 was enacted. At that time, the bank had $1.11 billion in unrestructured nonaccrual real estate loans. By year-end 1989, that figure had been reduced by 90 percent to $108 million. The bank currently holds 8,543 restructured real estate loans for $1.168 billion, the vast majority of which are performing in a satisfactory manner.

Many of these restructures were written for a three year period. About $365 million worth of these restructured loans need to be reviewed in 1990. Many of these borrowers had their interest rates reduced for three years to 8 or 9 percent, after which they would return to the prevailing market rate. undoubtedly some of these borrowers will not be financially able to return to market rates. In these cases, the bank will attempt to make more extensive use of the FmHA buydown guarantee programs.

Performance on maturing or repriced restructured real estate loans has been good. Seventy percent are in accrual status and another 21 percent are considered earning assets as interest income is generated when payments are made. Twenty percent carry an acceptable credit classificaiton and 94 percent are current in payment status. Less than 5 percent are in bankruptcy or foreclosure.

Overall, this group of loans has performed well and has shown improvement in financial condition and repayment capacity. Many have a reasonable chance for success but the bank estimates that at least one-third, or about $120 million worth of loans to around 750 borrowers, need the benefits of the FmHA guaranteed loan programs.

Testimony of Harold B. Steele
Chairman and Chief Executive Officer
Farm Credit Administration

Mr. Chairman and members of the Subcommittee, I am Harold B. Steele, Chairman and Chief Executive Officer of the Farm Credit Administration (FCA). With me is Marvin R. Duncan, a second member of the Farm Credit Administration Board. I am pleased to appear before you to discuss the role and responsibility of the FCA and the costs associated with the agency's regulatory mission.

The management of the FCA is vested in the Farm Credit Administration Board, whose three members are appointed by the President subject to confirmation by the U.S. Senate. The Board has operated with a quorum of two members since I assumed my present position on October 12, 1989. A third member has yet to be appointed.

The FCA is responsible for promoting the safety and soundness of Farm Credit System (FCS) institutions as they carry out their mission under the Farm Credit Act of 1971, as amended. Their mission is to provide credit and related services to farmers, ranchers, and their cooperatives. The FCA promulgates regulations and conducts evaluations of FCS institutions for compliance with applicable laws, regulations, and safe and sound banking practices. If an examination or other evaluation conducted by the FCA reveals that an institution is in violation of Federal law and/or regulations or is being operated in an unsafe or unsound manner, the agency undertakes one of several enforcement options at its disposal by which it effects corrective action. The FCA maintains a vigorous regulatory and examination program to ensure that the conditions preceding the recently implemented financial assistance do not recur.

I am here today to present the budget of the Farm Credit Administration for the fiscal year 1991. As one who has farmed for 42 years, I am fully aware that every dollar the FCA's budget represents must ultimately come from those who borrow from the institutions of the Farm Credit System, primarily American farmers, ranchers, and their cooperatives. And as Chairman and Chief Executive Officer of the Farm Credit Administration, I am equally aware that the prudent and wise expenditure of those dollars helps ensure that the institutions of the Farm Credit System operate in accordance with law, regulations, and safe and sound banking practices. Those expenditures also help ensure that the borrower-stockholders of FCS institutions and those who invest in the securities sold to raise loan funds are protected against loss.

Investors in Farm Credit Bank bonds are willing to accept lower rates if they perceive those bonds are sound investments. And lower bond rates translate into lower interest rates for borrowers. Investor perceptions are affected by bond ratings. For example, last October, Moody's Investors Service gave Farm Credit Bank bonds a triple A rating. In so doing, Moody's had the following comment about the Farm Credit Administration. "The focus of the FCA is ensuring the safety and soundness of the FCS, which it has pursued with vigor since the various statutes affecting the FCA were changed in 1985. In the past few years, the FCA has worked hard to expand and train its supervisory force, and to improve its examination procedures. This strengthened supervision of the FCS enhances FCS debtholder protection."

Does a favorable rating result in lower bond rates? To answer that question in part, on January 24, 1990, the Farm Credit Banks priced three bond issues. A 3-month issue totaling $1.35 billion was priced at 8.05 percent. A 6-month issue totaling $1.15 billion went for 8.125 percent. And a 12-month issue totaling $645 million carried a rate of 8.20 percent.

The 3- and 6-month bonds were 10 basis points over comparable U.S. Treasury issues, and the 12-month bonds were 2 basis points over comparable Treasuries. That tells me that investors consider Farm Credit Bank bonds very close to comparable Treasuries even though they do not carry the full faith and credit guarantee of the United States.

I do not know exactly what a triple A rating is worth. But if it resulted in bond costs being lowered just 20 basis points (two-tenths of one percent), the Farm Credit System would have realized an annualized savings of $6 million on those three issues alone. The annualized savings on the $14.0 billion in bonds sold since September 26, 1989, would have been $28 million.

The Moody's report is correct in its assertion that the FCA has focused on ensuring the safety and soundness of Farm Credit institutions and that we have pursued that responsibility with vigor. On December 31, 1989, there were 287 Farm Credit institutions, not including 11 in liquidation. During that year, 72 of those institutions, with combined assets of $53.3 billion, were operating under FCA enforcement documents.

To the credit of the boards of directors of these institutions, most of the enforcement documents were "consent" documents. That means that the boards agreed with the FCA's determination that operating deficiencies exist and are willing to take the steps necessary to correct those deficiencies.

Mr. Chairman, an important part of both our examination and enforcement activities is to offer boards and management of distressed institutions the tools necessary to rebuild those institutions. The Reports of Examination point out deficiencies, and enforcement documents set forth formal steps that need to be taken to correct those deficiencies. For those institutions that are healthy, our examination reports provide the boards with independent evaluations of capital adequacy, asset quality, management capability, earnings, and liquidity of their institutions.

Because the loan volume of the Farm Credit System has declined substantially in recent years and the number of institutions has also declined, it would outwardly appear that the FCA's work load should have decreased and its cost of operations should diminish accordingly. But the added responsibilities placed on the FCA as a result of enactment of the Farm Credit Amendments Act of 1985 and the Agricultural Credit Act of 1987 have precluded either from happening. On the contrary, those added responsibilities have caused a chain reaction from the recruitment and training of additional examiners to the redesigning of virtually every component of the agency's administrative support structure, e.g., data processing, telecommunications, budget and accounting, consolidated reporting, etc. Though we fully expect efficiencies to result in the long term, initial costs have to be borne as they are incurred.

There are several specific reasons why the decline in loan volume and in the fewer number of institutions have not translated to a directly proportional reduction in expenses.

° Institutions resulting from mergers are larger and more complex than their separate constituent institutions. Though these institutions may require somewhat less onsite examination time, the decline in the work load is not directly proportional to the decline in the number of institutions. If two associations merge, for example, onsite examination time may be decreased but because the resulting association is larger it is not cut in half.

- We are making efforts to economize by substituting some monitoring and evaluation activities for part of our onsite examination work. Those efforts have had significant development costs. The results in reduced examination costs, however, should be realized over the long term.
- A significant number of charter changes (mostly mergers, including the creation of 40 Agricultural Credit Associations) and major new areas of regulation development had to be undertaken. These activities, which are expected to continue, have required major amounts of staff time.
- FCA examinations conducted prior to 1985 concentrated almost exclusively on assessing credit quality and depended, in part, on credit reviews of associations conducted by the banks. The FCA now must examine every direct lending institution of the FCS at least once each year and conducts more full-scope examinations, examining such areas as capital adequacy, asset quality, management capability, earnings, and liquidity more vigorously.
- Regulation of the institutions has become more complex as a result of changes in the statutes and increased management sophistication. Examinations of capital adequacy and borrower rights are now required because of legislative changes. More sophisticated techniques on the part of managements in loan pricing, funding, and investment management have also increased the examination work load.
- The creation of Agricultural Credit Associations and Federal Land Credit Associations as direct local lenders

has increased the complexity of association examinations. The creation of these new associations has also resulted in the creation of new risks because managements are taking on the broader range of functions and powers related to having long-term real estate loans on their books rather than merely acting as agents for the banks.

° The creation of the Federal Agricultural Mortgage Corporation and the Farm Credit System Insurance Corporation has resulted in a greater work load, one that will increase as these two entities become fully operational.

° And those 72 institutions operating under enforcement documents require more frequent monitoring to ensure compliance with the requirements contained in those documents.

As I indicated earlier, the problems of FCS institutions of the 1980s have resulted in increased responsibilities for the FCA as mandated by the Congress. Those problems have also resulted in the need for financial assistance through the issuance of Government-guaranteed bonds. The estimated cost of that financial assistance to FCS institutions will add 27 basis points to the interest cost FCS borrowers must pay over the next 15 years. By comparison, the FY 1991 FCA budget is only about 8 basis points of borrowers' interest costs. I submit that is a small price to pay for the kind of regulatory and examination activity envisioned by the Congress to ensure the safety and soundness of FCS institutions and prevent those problems from recurring.

In both the 1985 and 1987 legislation, the Congress was emphatic in its judicious underlining of the FCA's responsibility for ensuring the safety and soundness of the institutions under its jurisdiction by requiring the direct annual examination of all direct lending institutions. Since enactment of the 1987 statute, 40 Agricultural Credit Associations and two Federal Land Credit Associations have been created, resulting in the downloading of long-term farm real estate loans from the banks to the associations. More such actions are in process, as are the reversals of some association mergers. When these activities are concluded, there will be more direct lending associations.

To carry out its mission of ensuring compliance with the law, regulations, and safe and sound banking practices, the Farm Credit Administration needs highly qualified, professionally competent, and properly motivated people. And the FCA is an organization of people. More than 85 percent of the current budget goes for salaries, personnel benefits, and travel. The agency's recruitment and examiner training program has proven to be exceedingly successful as shown by the quality and thoroughness of the examination process and the results that process has achieved. Most new examiners are recent college graduates. They are usually hired at the entry level and progress through the ranks as they undergo a 3- to 4-year formal and on-the-job training program culminating in a 4-day oral and written examination. Those who successfully complete this rigorous program become commissioned FCA examiners. The agency also requires highly skilled technical staff to develop regulations, carry out approvals required by law, charter institutions, impose and monitor enforcement actions, and provide legal, accounting, economic, financial, and other skills to these efforts.

As I indicated earlier, I entered into this responsibility just over four months ago. During that time, I have had the opportunity to observe and evaluate the agency's planning processes. I have been both pleased and uplifted by the positive aspects of those processes. I judge the specifics identified in the budget documents previously submitted to this committee to be essential steps if the agency is to carry out its mission in accordance with the law. I have also been impressed by a number of internal studies that were in process upon my arrival, most of which have been since completed. They address important areas of strategic planning and will be the underpinning of the agency's reaching its goals and attaining its objectives in a timely and efficient manner.

These internal studies identified 27 issues and subissues related to examination and enforcement activities. The 10 to which we gave the highest priority were summarized in the budget documents previously provided to this committee. Addressing these issues is essential to the successful mission of the agency. The agency is seeking to be more proactive in anticipating, preventing, and averting problems, both in individual institutions and in the FCS as a whole. Our financial analysis and projections functions stand alongside monitoring and onsite examinations as keys to a more efficient and effective FCA.

The Farm Credit Administration looks upon its assignment as a vital link in the chain that will drive the Farm Credit System forward and reestablish the entire entity as one that can provide credit services to American farmers, ranchers, and cooperatives in a professional, competitive, and service-oriented manner. We pledge to dedicate ourselves as analysts, examiners, and enforcers to providing boards of directors with rules and regulations, evaluations, and, when necessary, enforcement documents that will help them in directing the kinds of institutions that provide the credit services borrowers deserve in a safe and sound manner.

Achieving these goals is as important to me as a farmer as it is to me as Chairman of the FCA.

In both capacities, I recognize the importance of well-trained professional people. Earlier I mentioned the recruitment and training of FCA examiners and technical specialists. To protect the investment we have made in these people, as well as other staff, we granted a modest 3-percent salary increase and area cost-of-living differential to four FCA office locations on January 5, 1990. We felt these were necessary as initial steps toward attaining pay and benefits comparability with other Federal financial regulators.

In a determined effort to stay within the current FY 1990 budget, however, we also

- instituted a hiring freeze for the remainder of FY 1990, though staffing is at the lowest level in three years,
- reduced training by 16 percent, including reductions in all management and supervisory training,
- deferred 29 percent of planned purchases of computer hardware and 23 percent of software, and
- cancelled 23 percent of all professional book orders and publication subscriptions.

But we know these actions must be temporary if we are to successfully fulfill our assignment as an effective Federal regulator of financial institutions as set forth in the Farm Credit Act of 1971, as amended.

Mr. Chairman, I have indicated once or twice in this testimony that I wear two hats--one as a Federal regulator and the other as a farmer. But I want to hang those hats on the same rack, one that is located in a topnotch Farm Credit office.

I will be pleased to answer any questions on the fiscal year 1991 budget of the Farm Credit Administration.

FARM CREDIT ADMINISTRATION
Public Enterprise Funds
FY 1991 CONGRESSIONAL BUDGET REQUEST
(Dollars in thousands)

	FY 1990 Budget	Change	Proposed FY 1991 Budget
Obligations	36,120	5,428	41,548
Outlays	314	-1,020	-706
FTE Workyears	561	51	612

PURPOSE STATEMENT:
The Farm Credit Administration (FCA) is the independent Federal agency responsible for the examination, regulation, and regulatory enforcement of the borrower-owned, federally chartered Farm Credit Banks and associations and the various other institutions that make up the Farm Credit System (System).

Originally established as an independent agency by Executive Order No. 6084, effective May 27, 1933, the agency was transferred to the Department of Agriculture on July 1, 1939. It remained in the Department of Agriculture until the Farm Credit Act of 1953 reestablished it as an independent agency. The Farm Credit Act Amendments of 1985 altered the mission of the FCA, changing its role as a coordinator of Farm Credit Bank activities to that of an independent regulatory agency, and transferred to the FCA from the System responsibility for direct examination of all associations as well as the banks. The Agricultural Credit Act of 1987 clarified the regulatory and supervisory roles of the FCA and mandated an extensive reorganization of the System, while increasing the overall responsibilities of the FCA as a regulator.

The FCA is directed by a three-member, presidentially appointed Farm Credit Administration Board. The Board is responsible for FCA policy, regulation, promulgation, enforcement activities, and general oversight of agency operations.

All expenses for the activities and personnel of the FCA are paid from assessments collected from the institutions of the Farm Credit System based on annual budgets approved by the Farm Credit Administration Board.

JUSTIFICATION:
Prior to the formulation of the FY 1991 budget, the FCA conducted an intensive study to identify those issues and responsibilities generated by the Agricultural Credit Act of 1987 and prior legislation. Twenty-seven issues and subissues requiring resources beyond those routinely required for examination and enforcement activities provide the basis for the FY 1991 budget. Only those considered of the highest priority were included, among which the most critical are:

- Determining how a borrower stock should be treated for the purpose of allocating impairments.
- Defining the appropriate role for the FCA to play in resolving conflicts between Farm Credit Banks and associations and what interests should FCA seek to protect in the resolution of such conflicts.
- Revising the scope of bank supervision to distinguish it from FCA regulatory matters and to avoid unwarranted interference with the autonomy of an association.
- Assessing the appropriateness of current lending limits within the changed environment created by the 1987 Act.
- Redefining how the FCA should regulate the lending relationship between banks and associations to ensure that regulatory interests are protected and that the legitimate interests of banks and associations are adequately accommodated.
- Evaluating FCA's methodology in dealing with potential liquidations, including determining an appropriate definition of insolvency, exploring alternatives to receivership, and strengthening administration of receiverships.
- Determining what, if any, conditions the FCA should impose by regulation when an institution terminates its status in the System.
- Defining how the agency will address its responsibilities for regulation and supervision of Farmer Mac and Farm Credit institution poolers, as well as those secondary market issues that relate to System institutions that are loan originators.
- Establishing the financial, legal, and organizational framework of the Farm Credit System Insurance Corporation (FCSIC), the relationship of the FCSIC to FCA, and the appropriate scope of FCA's examination function.
- Developing a supervisory approach that is more predictive and facilitates prompt and effective responses.

Each of the issues noted above consists of numerous inter- and intrarelated components requiring involvement of virtually every office in order to assure that the legal, financial, and regulatory impacts are reconciled and that any resultant regulations accurately reflect FCA's position. In order to accomplish these objectives, it is estimated that approximately 11,920 staff-days, the equivalent of 52 full-time employees, will be required. Delay in resolving these issues could result in either a serious threat to the safety and soundness of System institutions or undermine FCA effectiveness.

In addition to the above, the Office of Financial Analysis has been operating with a significant number of unfunded vacancies for the past 2 years. Lack of staff has precluded proactive analyses of safety and soundness issues such as systemic risks, catastrophic risks from external causes, and development of tools for offsite monitoring and analysis of institutional risk. Other issues which will require analysis and closer surveillance over the next year include: the 1990 Farm Bill; the GATT negotiations; repeal of Glass-Steagall; and revised insurance programs for financial institutions, all of which will have implications for both the Farm Credit System and FCA as the System regulator.

A significant challenge for the Office of Examination in fiscal year 1991 will be resource planning and management in the changing organizational environment of the Farm Credit System. The challenge will be compounded because of the uncertainty of the timing and extent of Farm Credit System organizational changes. Certain changes, like converting districtwide associations into numerous smaller local associations, would increase the need for staff resources to carry out the office mission. Conversely, other changes, such as mergers and consolidation, would likely decrease resource needs. In conjunction with the organizational uncertainty, the Office of Examination must plan and manage resources within budgetary constraints so that its defined mission is effectively and efficiently attained.

Finally, the downloading of assets to associations by district banks can be anticipated to create a significant number of associations that may require some form of enforcement action.

Since FY 1987, the FCA has absorbed four employee cost-of-living increases, a 25-percent increase in employee benefits (due to the implementation of FERS), and the cumulative effect of inflation on the cost of goods and services. Furthermore, the FCA has absorbed the added costs of travel related to its examination and regulatory activities resulting from three Government per diem rate increases. During the same period, overall expenses have increased by 9.2 percent.

The budget for FY 1991 reflects the resources required to address the critical issues noted previously, a reinstatement of line items reduced, deferred, or canceled for FY 1990, and the funds necessary to attempt to maintain pay comparability with other financial regulators in accordance with Public Law 101-73, the Financial Institutions Reform, Recovery, and Enforcement Act of 1989. The FCA will continue to reduce costs wherever possible but cannot continue to fulfill its ever-expanding statutorily mandated mission without an increase in operating expenses in FY 1991.

Since passage of the Agricultural Credit Act of 1987, the structure of the System has been in a continuous state of reorganization through mergers and creation of new entities. As a result, the basis for allocation of assessments is no longer applicable. A study is currently in process to determine the most equitable basis for future assessments of all institutions including the Federal Agricultural Mortgage Corporation (FAMC). Although some resources have been expended by FCA in monitoring and working with FAMC, no secondary market activity by FAMC has taken place that would permit an assessment; hence, FCA has neither asked for nor received any funds from FAMC.

The following is an explanation of the projected cost increases from FY 1990 to FY 1991.

FARM CREDIT ADMINISTRATION
Administrative Expenses
(Dollars in thousands)

	Amount
FY 1990 BUDGET (APPROVED)	$36,120
INCREASES/DECREASES BY OBJECT CLASS	
Personnel Compensation and Benefits:	
° Annualization and continuation of effort to achieve pay comparability with financial regulators and return to adequate staffing levels.	3,521
° Benefits cost increases reflect the continuing impact of FERS, the increase in FICA taxes, and rising health insurance costs.	743
Travel and Transportation of Persons:	
° FCA examiners, representing about 55 percent of the workforce, travel nearly 70 percent of their time. Increased cost reflects inflation of airline rates, increased Government per diem which reflects inflation, and includes travel related to Commissioned Examiner training and testing.	605
Transportation of Things:	
° Modest increase reflects the inflation of costs of transportation services including applicable charges in this category for employee relocation.	5
Communications, Utilities, and Other Rents:	
° Increased costs of communications including telephone and postage expenses.	128
Printing and Reproduction:	
° Increased costs in printing associated with the issuance of regulations, examination reports, and other bank and association data.	24
Other Services:	
° Primarily an increase in the cost of computer services related to the enhanced capacity for automatic data processing and the network for handling bank and association financial data.	303

Supplies and Materials:

° Efficiencies and savings in administrative materials and expenses.	-26

Equipment:

° Cost of hardware purchases and leases to upgrade ADP capacity and operations and continue the replacement of mature equipment.	125
FY 1991 BUDGET REQUEST	$41,548

FARM CREDIT INSURANCE FUND:
On December 31, 1968, the Farm Credit Banks retired the Federal Government's investment in the Farm Credit System. The proceeds from this action were deposited into two funds: the Short-Term Credit Investment Fund and the Banks for Cooperatives Fund, which were merged into a single investment fund by the Farm Credit Act of 1971. The Agricultural Credit Act of 1987 made these funds available to the Farm Credit Assistance Board (FCAB) to provide assistance to Farm Credit institutions on an interim basis prior to the issuance of obligations. Funds so used were paid back into the Revolving Fund from the proceeds of FCAB-issued obligations. In January 1989, this fund in the amount of $259,798,716 was transferred to the Farm Credit Insurance Corporation for use in insuring obligations of System institutions.

FARM CREDIT ADMINISTRATION
Administrative Expenses
Object Classification Schedule
(dollars in thousands)

Object Class	FY 1990 Budget	Change	FY 1991 Estimated
Personnel compensation			
Full-time permanent	$21,974	$3,394	$25,368
Other than full-time permanent	698	22	720
Other personnel compensation	350	105	455
Special personal services payments	0	0	0
Total personnel compensation	23,022	3,521	26,543
Personnel benefits: Civilian	5,322	743	6,075
Benefits for former personnel	0	0	0
Travel and transportation of persons	3,629	605	4,234
Transportation of things	109	5	114
Communications, utilities, and other rent	868	128	996
Printing and reproduction	168	24	192
Other services	1,712	303	2,015
Supplies and materials	649	-26	623
Equipment	631	125	756
Total obligations	$36,120	$5,428	$41,548

TESTIMONY
OF
ERIC P. THOR, PRESIDENT AND CEO
FARM CREDIT SYSTEM ASSISTANCE BOARD
BEFORE THE SUBCOMMITTEE ON
RURAL DEVELOPMENT, AGRICULTURE, AND RELATED AGENCIES
FEBRUARY 27, 1990

Mr. Chairman, distinguished Subcommittee Members, it's a pleasure to appear before you today to talk about the Assistance Board and the progress we and the Farm Credit System institutions have made to improve agricultural credit for farmers and ranchers throughout the United States.

The financial assistance mechanism of the Agricultural Credit Act of 1987 is working. Just over two years after passage of the Act designed to rescue the Farm Credit System from financial disaster, that System is on its way to again becoming a stable, dependable agricultural lender for rural Americans. Although they were crippled during the early 1980s, those Farm Credit System institutions which have received assistance are today making progress toward long-term viability. Working through the assistance process, which all of you put in place, the System, with help from the Assistance Board, has improved credit service to over 225,000 farmers and ranchers in 15 states who produce over one-third of the nation's agricultural products by volume.

To accomplish this, the Assistance Board and the assisted institutions have to date used under a billion dollars -less than a quarter of the four billion dollars authorized by the Congress. It is too early to determine how much of that authorization will be needed.

In addition, the Assistance Board has lowered its administrative budget for fiscal year 1991. As you know, the Assistance Board does not use appropriated funds to support its operations. Farm Credit System Financial Assistance Corporation (FAC) bonds issued to fund the financial assistance to System institutions also fund our administrative expenses. The interest on these bonds is paid jointly by the System and the U.S. Treasury, for which you appropriate funds. Upon maturity, the bond principal along with all interest initially funded by the Treasury, will be repaid by System entities as defined by the statute.

ASSISTANCE TO FARM CREDIT SYSTEM INSTITUTIONS

To date, the Assistance Board has certified the Farm Credit Banks of Louisville, Omaha, and St. Paul as eligible to receive financial assistance of just over $333 million. In addition, the Assistance Board provided the Federal Land Bank of Jackson in

Receivership with approximately $45 million in initial financial assistance to enable the bank to retire borrower stock and avoid default on its debt. The System also received $415.4 million as part of the capital preservation agreements made during 1986. The remainder of the total $847 million of FAC bonds outstanding went to fund various other assistance-related items, including Assistance Board expenses and borrower stock.

The key to these assistance packages is the agreement forged between each applicant institution and the Assistance Board. The agreement implements the Assistance Board's statutory authority to monitor compliance with and require changes in the bank's business and recovery plan. This plan is the basic requirement of any assistance application. Before the Assistance Board authorizes any financial assistance, an applicant bank must develop and present a realistic, well-thought-out plan for recovery. We view the development of such a plan as an indicator of the ability of the bank's board and management to assess its financial problems, to know the measures needed to correct them, and to implement the plan once adopted.

After a Farm Credit institution has been certified for assistance, the Assistance Board requires the institution to submit an annual update of its business and recovery plan. As part of our approval process, we can require any modification necessary to ensure the continued progress of the institution toward viability and the eventual repayment of the assistance provided. Throughout the year, the Assistance Board monitors the bank's compliance with its approved plan.

ASSISTANCE BOARD MONITORING AND CERTIFIED INSTITUTION PROGRESS

During 1989, and continuing into 1990, the Assistance Board is concentrating its resources on monitoring and analyzing the financial progress of assisted institutions. Each month, the Assistance Board reviews the certified institutions' financial condition and their performance against their annual business and recovery plans. Also, the Assistance Board makes regular visits to each certified district to meet with each bank's board and management, and FCA field examiners. We continue to meet with farmers and ranchers throughout the country to solicit their opinions toward the System's service and structure. These meetings have been vital to our decision making and monitoring processes.

Certified institutions' management and boards have implemented strategies to return their respective institutions to sound banking principles. The institutions have focused new attention on lowering overhead while improving service to customers and streamlining the credit delivery system in each district. These steps, along with a restructuring of the institutions' liabilities and an improving interest rate environment during the last half of 1989, lowered the final cost of credit to the farmers and ranchers during the year. This return to banking fundamentals paid off in 1989, as all three of the certified institutions outperformed their respective business and recovery plans in most major categories.

Certified institutions have placed additional emphasis on asset and liability management, the process of matching each institution's funding needs to its particular loan portfolio. System managers are exploring new avenues to avoid the funding mismatch that occurred in the early and mid 1980s. During the period of historically high interest rates in the early 1980s, the System sold large amounts of non-callable, high-coupon, long-term bonds at rates in excess of thirteen percent. When interest rates fell, the System was unable to compete because its cost of funds remained high. We are all familiar with the problems that followed, culminating in the passage of three separate Farm Credit Acts and finally, with the 1987 Act, the creation of the Assistance Board.

Great strides have been made in the System's asset/liability management practices. The certified institutions are now better prepared to deal with the fluctuations of a volatile interest rate environment. The Assistance Board requires each certified institution to know and understand the impact on the bank of sharply rising or falling interest rates. As a result, boards of directors are improving policies limiting their bank's risk in these environments. Nevertheless, much work remains.

Further evidence of the certified institutions' progress toward viability is their success in reducing their non-earning assets. In 1987 the St. Paul, Louisville, and Omaha banks, in total, had $1.8 billion of nonaccrual loans and $358.3 million of acquired property, for a total of approximately $2.2 billion of non-earning assets. By the end of 1989, the three banks had reduced these non-earning assets to a combined total of $680 million, a reduction of 69 percent. Each bank is predicting further reductions in this category for 1990.

Progress has also been made in the three states formerly served by the Federal Land Bank of Jackson, now in receivership. Since the FCA placed the Jackson Bank into receivership, farmers in the area have regained access to a source of stable long-term lending at substantially lower rates than were available prior to the receivership. The FCA has recently chartered six new Federal Land Bank Associations, two each in Alabama, Mississippi, and Louisiana to serve the area's real estate lending needs. Progress toward resolving the receivership continues. We are aware that an agreement in principle to dispose of the receivership's remaining assets has been reached between the FCA and System representatives. We are urging both parties to quickly resolve the matter.

As we mentioned last year we are ever mindful that the investment community is watching the Farm Credit System recovery process. On average, increased investor confidence in the System has further narrowed spreads approximately 10 - 20 basis points from last year. The System's total debt of approximately $55 million should benefit from these narrowed spreads, saving the System and the U.S. taxpayer hundreds of millions over the next years. We continue to remain watchful of investor interest in Farm Credit securities.

Each of the certified institutions has met the interim regulatory capital adequacy standards and is making progress toward permanent regulatory capital adequacy standards. In addition, all certified banks have a mechanism in place to set aside earnings to repay the financial assistance received.

Certified institutions are required to uphold the borrower rights provisions of the 1987 Act. Those provisions directed the Assistance Board to establish the National Special Asset Council to monitor loan restructuring activity in the certified institutions. The Council examines each certified institution to ensure that the institutions comply with the borrower rights provisions of the law. To date, the Council has found that the assisted institutions are taking the actions prescribed by the 1987 Act.

Though the majority of the certified banks' financial indicators show great improvement, concerns remain. Generally, operating expense in relation to loan volume in System institutions remains high. Non-earning assets, while substantially reduced, remain high in comparison with commercial banks and other financial institutions. Capital levels within the certified institutions are not yet rebuilt to a solid level, although steps are being taken to do so. Accrual loan volume in the certified institutions, and the System as a whole, continues to fall short of projections. In 1985, the total combined accrual loan volume of the three now-certified banks was approximately $19 billion. At the end of 1988 accrual loan volume in these institutions had fallen to $11.9 billion. We are encouraged to note that, by the end of 1989, accrual loan volume in the certified institutions had risen slightly, to just over $12 billion. The rest of the System's accrual loan volume followed a similar pattern. In 1985, the System's total accrual loan volume was $64.7 billion. The System total fell to $48 billion in 1988 and then remained stable during 1989. During 1990, all of the certified institutions will focus on solving these remaining problems.

The FCA informed us that the Farm Credit Bank of Spokane is impaired, making them eligible to apply to the Assistance Board for financial assistance. To date, we have not received a request from the Spokane Bank. Until or unless an assistance request is received, the Assistance Board is limited to monitoring the Bank's financial condition.

The System's institutions also face some problems which are out of their control. Food safety, global warming, environmental dangers, cash flow of farmers, or any other issue which could threaten cash farm income also threatens the Farm Credit System. Land values, while today they continue their climb back from the levels of 1985 and 1986, could again fall. The Assistance Board has asked each certified institution to assess the steps it would take tc avoid the possible dangers which these issues present.

ASSISTANCE BOARD STRUCTURE

It is the Assistance Board's task to help ensure that these banks continue the progress I have just described. To accomplish this, we have a small staff which carries out the monitoring and assistance functions prescribed by our Board of Directors. As set forth in the 1987 Act, our Board of Directors consists of the Secretaries of Agriculture and the Treasury and a producing farmer nominated by the President and confirmed by the Senate. Currently serving are Secretary of Agriculture Clayton Yeutter, who serves as chairman, Secretary of the Treasury Nicholas Brady or his designee, and William W. Erwin of Indiana.

Because we have stressed cost reduction to every institution requesting assistance, the Assistance Board has been very cognizant of its own internal administrative budget. With this conservative principle in mind, the Assistance Board will reduce its administrative budget for fiscal year 1991 to $2.184 million, a one percent decrease from the fiscal year 1990 level.

FINANCIAL ASSISTANCE CORPORATION

As I mentioned before, the Assistance Board does not use appropriated funds to support its operation. Instead, as I described, we depend upon the proceeds of FAC bond sales to fund the financial assistance. With the timely payment of principal and interest guaranteed by the Secretary of the Treasury, FAC bonds enjoy significantly lower rates than non-U.S. Government-backed bonds. FAC bonds have a 15-year maturity and pay interest semi-annually.

Interest payments on FAC bonds used to fund the assistance packages and System borrower stock are made solely by the Treasury for the first five years. For the second five years, interest is split nominally by the Treasury and the System. The remainder of interest and, upon maturity, the principal is also funded by the System. In addition, all interest initially funded by the Treasury will be repaid by the System.

Some FAC bonds were sold to fund other types of assistance authorized as part of the old System capital preservation agreements. All interest and principal payments on these bonds are made by the System. I have attached a table showing the amount, uses, and repayment structure of FAC bonds already sold.

OUTLOOK FOR 1990

Mr. Chairman, in the coming year, the Assistance Board will continue to concentrate on monitoring assisted institutions and improving the agricultural credit situation for the nation's farmers and ranchers. The Farm Credit System has made great progress during the past two years and we commend them for it. We remind everyone however, that the return to financial viability is not complete and is always subject to possible reversal as a result of another drop in land values or severe adverse climatic conditions. Much work remains ahead if the System is to be restored as a provider of competitive agricultural credit to the nation's farmers and ranchers. The Assistance Board will continue to provide financial assistance as necessary to enable System institutions to return to financial health.

Thank you Mr. Chairman. I will be happy to respond to any questions you or your fellow subcommittee members may have.

ATTACHMENT

Financial Assistance Corporation Expenditures
As of January 31, 1989

Use of Proceeds	Amount	Payment of Interest	Repayment of Principal
Third Quarter 1986 Capital Preservation cash outs for Louisville, Omaha, St. Paul, and Jackson	$415,442,088	System Institutions	System Institutions
Provide Financial Assistance	$370,554,670	U.S. Treasury & System Institutions	System Institutions
Retirement of Frozen Borrower Stock	$ 21,026,795	U.S. Treasury & System Institutions	System Institutions
Assistance Board Expenses	$ 3,079,009	U.S. Treasury & System Institutions	System Institutions
Interest on Promissory Notes Payable	$ 563,498	U.S. Treasury & System Institutions	System Institutions
Discount of First Bond Sale	$ 2,250,000	U.S. Treasury & System Institutions	System Institutions
Prefunding	$ 34,083,940	U.S. Treasury & System Institutions	System Institutions
Total FAC Bonds Issued	$847,000,000		

Note: Amounts have been rounded to the nearest dollar. Chart compiled from Financial Assistance Corporation and Assistance Board documents.

FARM CREDIT SYSTEM ASSISTANCE BOARD
FY-1991 Budget Request

For FY-1991, the Assistance Board will require $2,184,000 for administrative expenses and support of the National Special Asset Council and the appointed board member. This is a reduction from FY-1990. Key elements of this request are:

- Amounts for compensation and benefits to support the same staff level as FY-1990. This includes the appointed board member. ($1,490,000)
- Travel, which remains a key element to successful program execution, is reduced from FY-1990. This amount includes travel of the appointed board member, the National Special Asset Council, and Assistance Board staff. ($117,500)
- Amounts to support contracts and training for staff operations, a reserve for potential expenses related to audits of system bank operations, and contracts related to the National Special Asset Council. ($322,800)

FARM CREDIT SYSTEM ASSISTANCE BOARD
FY-1991 Budget Request

	OBJECT CLASS	AMOUNT
11	Personnel Compensation	$1,266,000
12	Personnel Benefits	224,000
21	Travel	117,500
22	Transportation of Things	2,400
23	Rent, Communication and Utilities	203,000
24	Printing	8,600
25	Other Services	322,800
26	Supplies and Materials	33,400
31	Equipment	6,300
	Total:	$2,184,000

Financial Assistance Corporation Expenditures
As of January 31, 1989

Use of Proceeds	Amount	Payment of Interest	Repayment of Principal
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Total FAC Bonds Issued	$847,000,000		

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THURSDAY, MARCH 22, 1990.

COMMODITY FUTURES TRADING COMMISSION

WITNESSES

DR. WENDY L. GRAMM, CHAIRMAN, COMMODITY FUTURES TRADING COMMISSION

DONALD L. TENDICK, ACTING EXECUTIVE DIRECTOR

MADGE BOLINGER, BUDGET DIRECTOR

Mr. WHITTEN. I am sorry to have delayed this hearing, but it kept looking like things would come to a head on the floor. When lawyers get to arguing about the law it goes on and on. [Laughter.]

We have today the Commodity Futures Trading Commission, Dr. Wendy L. Gramm, Chairman, and associates. We will be glad to hear from you at this time.

BUDGET REQUEST

Dr. GRAMM. Thank you very much, Mr. Chairman and members of the subcommittee. I appreciate the opportunity to appear here today to summarize the fiscal year 1991 budget request of the Commodity Futures Trading Commission.

With me today are Donald Tendick, the Acting Executive Director of the Commission; and Madge Bolinger, our Budget Director.

The President's fiscal year 1991 budget, which was submitted to Congress in January of 1990, contains a request for $44,960,000 which provides for 595 staff-years and a mainframe computer upgrade for the Commission.

Based on the events of the last year, I believe that the funding of the requested level is essential if the Commission is to carry out its legislative mandate and fulfill its regulatory responsibilities adequately.

The last year was an unprecedented one for the Commission, beginning with a public announcement of major investigations of floor trading at the Chicago and New York Exchanges. So far the Chicago investigation has led to the indictment of 48 individuals.

Other important events of 1989 and early 1990 include an emergency action in the soybean pit, a sudden and large decline in the stock market during October, and the bankruptcy of Drexel Burnham Lambert Group. We also have continued to work with Congress on our reauthorization legislation.

The Commission is aware of the current fiscal restraints contained in the Federal budget; however, we feel that the law enforcement, trade practice abuse, and floor surveillance problems recently made public demand that the Commission increase both its enforcement and other resources to monitor the daily trading activities on the nation's commodity exchanges.

These increased resources are necessary to ensure that hedgers and other market users have their trades executed at the prevailing market price without abuse.

More computer support is also needed to conduct trade practice surveillance and support investigations.

The Commission's clear need for additional funding and staffing has been widely supported by Congress in recent reauthorization hearings, as well as by the Administration in granting CFTC a funding and staffing increase in the President's fiscal year 1991 budget.

SUPPLEMENTAL APPROPRIATION

However, the Commission needs resources now, and therefore we filed a request with OMB for a fiscal year 1990 supplemental appropriation of $3,655,000 providing for 25 staff-years to address more quickly some of the problems identified.

Already we have expanded our trade practice surveillance program, which includes trading floor surveillance, rule enforcement reviews, and trade practice investigations.

Other Commission programs—financial oversight, market surveillance, and law enforcement—complement and augment the Commission's trade practice surveillance program to assure that trading is fair and efficient and to help maintain the financial integrity of and public confidence in the markets.

ENFORCEMENT ACTIVITIES

During the past year, enforcement activities focused public and Congressional attention on self-regulation in the commodity futures and options markets and on the Commission's oversight regulation. In addition to the much-publicized Chicago and New York investigations, we also took other significant actions.

Injunctive complaints were filed against the International Trading Group, Ltd., and Siegel Trading Company for fraudulent sales practices. The ITG action is the largest enforcement action to prohibit a firm from using fraudulent sales practices in CFTC history.

The Commission filed a 19-count administrative complaint against Philipp Brothers, Inc. and others for violations of the Commodity Exchange Act and Commission regulations. A $4 million civil penalty was imposed, representing the largest fine in CFTC history.

SURVEILLANCE

The market surveillance program faced major challenges during fiscal year 1989. Most significantly, substantial position concentrations by a large trader and the Chicago Board of Trade soybean futures led to intensified surveillance actions by the Commission and ultimately the declaration of a market emergency by CBT on July 11, 1989. Both CFTC and CBT surveillance staff closely monitored the market daily and issued formal, non-public warnings to Ferruzzi, a large trader in the soybean futures pit.

Since liquidation was not occurring and since neither the CBT nor the Commission had assurances that it would occur in a timely fashion, the CBT declared a market emergency and ordered a scheduled liquidation of the positions in the July, 1989, soybean futures contract. The Commission thoroughly reviewed the events surrounding this emergency action and found the exchange acted in accordance with its rules and responsibilities.

Our surveillance staff also examined closely the price decline in the October, 1989, stock market. We continue to work closely with the SEC and other members of the Presidential Working Group on Financial Markets to ensure the integrity of the country's financial markets.

OVERSIGHT ACTIVITIES

During the year we increased and improved our oversight activities and increased direct regulation of exchange activities and programs. For example, we reviewed exchange audit trail systems. The audit trail rule requires the execution times of all trades to be determined to the minute, and we recommended that each exchange improve the accuracy and verifiability of its system and better use trade timing information to detect potential trade practice abuses.

The Commission also recently approved rules regarding trading cards and trading records to prevent alteration of these records and approved rules to bar individuals with disciplinary histories from serving on exchange disciplinary committees, arbitration panels, and governing boards.

The staff also has completed a study of trading practices of broker associations and is drafting a rule to define broker associations and require registration of broker association members.

In addition, we are preparing rules regarding all orders and procedures at the opening and closing of a trading session.

Based upon our study of dual trading and given information learned through the Chicago undercover operations, the Commission has proposed rules that would restrict dual trading. Our staff will continue to analyze data while implementing any rules to ensure that the restriction does not impose unnecessary costs or have unexpected side effects.

Mr. Chairman, given the challenges which will continue to confront the Commission, I believe the fiscal year 1991 budget request before you is a necessary one.

A lengthier written statement accompanies my oral remarks and provides more detailed descriptions of the Commission's priorities.

Thank you. I will be happy to answer any questions you may have.

[CLERK'S NOTE.—The biographical sketch of Mr. Tendick appears on page 265. The prepared statement of Dr. Gramm appears on pages 266 through 281. The explanatory notes appear on pages 282 through 410.]

Mr. WHITTEN. Thank you very much. I appreciate your appearance here.

What is the status of your reauthorization? Is it under study now as to what changes may be necessary?

REAUTHORIZATION BILL

Dr. GRAMM. The authorization bill is one that has already been passed by the House and there is one now being considered in the

Senate. It has not gotten through the Senate floor yet. But the authorities in both those bills are strong authorities that we feel are necessary to help us maintain the integrity of the markets—in particular, in response to what we have found after the FBI investigations.

Mr. WHITTEN. I don't know what the score is, and I don't profess to be an expert about markets but it certainly appears in recent years that the change made some years ago has not worked out as well as expected. I am aware that there is quite a feeling that we need to consolidate CFTC with SEC and provide closer supervision.

As I understand it, in a broad way they have let you be guardian of your own operations for the last number of years. What bothers me is that the press is reporting violations of insider trading before we are made aware of the problems. I understand that hedging is quite necessary and that gambling is, to some degree, also necessary. But it looks like with the problem of insider trading and other market violations that we read about, we need to make some change in oversight method which would bring this thing to a head. Do you have any suggestions as to any change in the law that would help matters?

Dr. GRAMM. There are a number of authorities in our reauthorization——

Mr. WHITTEN. Your fiscal year 1991 budget requests a substantial increase in dollars and staff, but what change in your operations would help straighten out the problems we have?

Dr. GRAMM. Increased staffing——

Mr. WHITTEN. Everybody wants more money and staff.

Dr. GRAMM. Right.

Mr. WHITTEN. This subcommittee happens to deal with agriculture. We have had folks testify and say nothing about farmers, or about agriculture at all.

Dr. GRAMM. Right.

Mr. WHITTEN. But they all want more money for programs other than those which support agriculture.

I just recently read an article describing the situation in the Mississippi Delta. Just about every small town down there has dried up and nobody is talking about doing anything to straighten it out. Again, I am no expert at this, but it looks like since we started regulating our own regulators we have had a bad system.

Dr. GRAMM. I am not sure that we have a bad system, but I would agree that there are changes that need to be made, and we are making a number of those changes to require some direct——

Mr. WHITTEN. You are asking for more money and more people. What can you do with what you already have to improve the way the Commission is being operated?

Dr. GRAMM. We are writing regulations, for example, and we, in our reauthorization——

Mr. WHITTEN. We already have regulations in place that are being abused. Do we need some continual spot checks, or——

Dr. GRAMM. That is right. One of the——

Mr. WHITTEN. I'll ask you again; putting the additional money and people aside, what can you do about your own operations that will improve this situation?

FLOOR SURVEILLANCE

Dr. **Gramm**. We are doing more floor surveillance, drafting regulations that would require more careful monitoring, and eliminate the ability to alter trading cards, which has been a problem on the exchanges. We are asking for the authority, to register people on the floor and revoke their registration if they violate the Act.

A number of these proposals are in our authorization packages. The ability to impose larger civil penalties and other sanctions, as well.

But you are right, there are a number of rules that we are writing, and are in the process of undertaking more direct regulation at this point in time. We are tightening the audit trail.

But we are also asking for additional resources to have more direct surveillance of floor activity.

Mr. **Whitten**. In your opinion, what seems to be the bog down in the legislative committees proceeding to get your reauthorization through? Is it a case of wanting to return to the old system where you spot checked and a whole lot of things that worked for years? It looks like CFTC has worked opposite to what was intended.

Dr. **Gramm**. I think that there is widespread support for our reform authorities that are in our reauthorization package. I do think that, like every reauthorization year that has occurred since the agency was formed, we have another jurisdictional issue where the SEC has some interest in having jurisdiction over either stock index futures or all the financial futures.

There have been proposals of that nature, and I think that is what is perhaps causing more of the delay at this point in time as compared with the other reform legislation in our reauthorization package.

Mr. **Whitten**. In reading your statement I noticed that a joint undercover investigation resulted in the indictment of 47 traders and 1 runner in Chicago. To build up to that big a problem it looks like somebody has been getting by with a good many things for a long time.

Dr. **Gramm**. We are very aggressive in seeking out fraud and abuse. What happened on the Chicago floors, you understand, was the use of undercover techniques to determine the extent people were able to get around our existing rules, our existing audit trail, for example, which is relatively new to the floors.

One of the things we did find out was that people were able to get around the audit trail through the use of accommodating brokers—things that aren't necessarily detectable with the existing audit trails.

Mr. **Whitten**. Would we be better to employ more folks in the prosecutor's office in the Department of Justice as opposed to your agency in view of what has been discovered in the last number of years?

Dr. **Gramm**. This has been a cooperative effort with not only the prosecutor's office——

Mr. **Whitten**. I am just asking which we should strengthen, the Department of Justice or your agency?

Dr. **Gramm**. One thing that came out in the undercover investigation and discussions with the FBI undercover agents was that more CFTC personnel on the floor would be valuable as a deterrent. That is one recommendation that, very frankly, we had been somewhat skeptical of before until we learned more.

Mr. WHITTEN. What is disturbing to me—and I shall not pursue this—but it looks like, if you study history, we are in one of those periods that preceded the last depression where everybody was dealing in the right to bid or the right to buy. Speculation was rampant.

SUPPLEMENTAL REQUEST

Dr. Gramm, on February 2 you requested of OMB a supplemental request for fiscal year 1990 of $3,655,000 and 25 staff years. What is the status of this request? Do you expect OMB to submit the request to Congress?

Dr. GRAMM. In accordance with the Commodity Exchange Act the supplemental request was presented to both OMB and Congress. As of this date the request is still pending. The Commission has not received any official word from OMB on their plans regarding this request.

Mr. WHITTEN. The fiscal year 1990 supplemental request is broken into two pieces: one is $2,000,000 to purchase a mainframe computer for new ADP requirements; and the second is for the restoration of cuts made by Gramm-Rudman. Are you aware of any other agencies that have requested funds to restore cuts made by Gramm-Rudman?

Dr. GRAMM. I am unaware of any other requests by agencies for funding solely to restore the cuts made by Gramm-Rudman. The single largest cause for a reduction in our FY 1990 staffing level has been the absorption of $1.3 million in pay costs.

Mr. WHITTEN. For the record, please provide the details on the activity the additional staff requested would perform.

Dr. GRAMM. The Commission sees an urgent need to increase immediately the level of trade practice surveillance, floor surveillance and investigation and prosecution of trade practice abuses, and to analyze and implement various proposals for strengthened regulations. These are the areas to which the additional 25 staff-years would be devoted.

TRANSACTION FEE

Mr. WHITTEN. The President's budget states that beginning in 1991 CFTC will charge 11 cents per transaction to cover CFTC operations. Please give us the details of the proposal. Why was 11 cents chosen? What is the status of this proposal?

Dr. GRAMM. The 11 cents per transaction proposal was made by OMB. OMB has informed Commission staff that the 11 cents figure was based upon the desire to generate approximately $41 million in fees for FY 1991. Our understanding of this proposal is that based upon the anticipated futures and option volume for FY 1991 the 11 cents per transaction fee would generate approximately $41 million. The status of this proposal has not changed since it was presented in the President's budget.

JURISDICTIONAL CHANGE

Mr. **Whitten**. Dr. Gramm, there have been a series of statements made in the area press by individuals concerning the operation of CFTC lately. Several of them suggest that CFTC, if not abolished, at least should be reduced in size with a major portion of your activity turned over to the SEC. Certainly, some of the original intent of CFTC's operation and its predecessor organization under the CEA was to look at commodities more in the line of agricultural commodities rather than financial instruments. Now, since only a small percentage of trades made in the exchanges concern agricultural commodities, why wouldn't it be better to give SEC the authority to take over everything except the agricultural commodities as it was in the past?

Dr. **Gramm**. In 1974, the CEA regulated only domestic agricultural futures contracts. Other futures, including precious metals, coffee, sugar, cocoa, lumber products, petroleum products and the new foreign currency futures, were unregulated. In creating an independent CFTC in 1974, Congress recognized that all these futures markets operate in the same way to perform the same unique risk-shifting and price discovery functions. The same basic regulatory principles apply whether you're trading corn, crude oil or financial futures. It is important to remember that financial futures were under development in 1974 and were specifically considered in the Congressional deliberations which led to vesting the CFTC with exclusive jurisdiction over all futures trading, regardless of the underlying commodity, service, right or interest. Congress recognized that it only makes sense to have a single regulator for this unique economic function.

Those who suggest splitting jurisdiction over futures trading between the SEC and the CFTC do not recognize that the CFTC regulates exchanges, not just contracts. The same people meet on the same trading floor subject to a single set of regulations governing customer protection, financial standards, trade practices, audit trails, clearing and settlement procedures, reporting, recordkeeping, and so on. The differences from contract to contract, for example, delivery procedures, are by comparison negligible.

Splitting jurisdiction on one exchange floor between two different regulators would create a whole host of regulatory overlaps and conflicts. For example, exchange rules would require SEC approval as to some contracts and CFTC approval as to others. The exchange, its members and clearing members would be subject to two different reporting, oversight and auditing systems for the same trading activity, and so on. Having two different regulators on the same exchange floor cannot work. It is a prescription for regulatory chaos.

Split jurisdiction would create other problems as well. For example, a cash market regulator, who would generally favor stable or higher cash market prices, has a potential conflict of interest in exercising authority over a futures market, where the regulator must be price neutral. Another concern is that giving the SEC authority over everything except agricultural futures would create an immediate demand at the SEC for people with regulatory expertise in futures markets. The most likely way to fill that demand is by raiding the CFTC's staff of seasoned and experienced futures experts, leaving behind a severely weakened and demoralized CFTC to try to regulate the agricultural contracts. These are serious concerns. But the real bottom line is that having two different regulators on the same exchange floor just will not work, any more than having two referees working the same ball game, each using the rulebook for a different sport.

OBJECT CLASSIFICATION

Mr. **Whitten**. Please provide an object class table that reflects your budget amendment request for fiscal year 1990, along with your request for fiscal year 1991.

Dr. **Gramm**. I would be happy to provide an object class table reflecting our budget amendment request.

[The information follows:]

COMMODITY FUTURES TRADING COMMISSION—OBJECT CLASSIFICATION

[Dollars in thousands]

	Identification code: 95-1400-0-1-376	Fiscal year— 1990 estimate	Fiscal year— 1991 request
11.1	Full-time permanent compensation	21,402	24,915
11.3	Other than permanent compensation	1,362	1,262
11.5	Other personnel compensation	755	799
11.8	Special personnel services payments	0	20
11.9	Total personnel compensation	23,519	26,996
12.1	Personnel benefits: civilian	4,292	5,274
13.0	Benefits for former personnel	24	0
21.0	Travel and transportation of persons	749	905
22.0	Transportation of things	17	19
23.2	Rental payments to others	5,053	5,249
23.3	Communications, utilities and miscellaneous charges	1,451	1,498
24.0	Printing and reproduction	227	216
25.0	Other services	2,320	2,178
26.0	Supplies and materials	624	603
31.0	Equipment	2,565	2,022
42.0	Payment under equal access to Justice Act	0	0
99.0	Subtotal, direct obligations	40,841	44,960
99.0	Reimbursable	20	20
99.0	Total obligations	40,861	44,980

FOREIGN INVESTIGATIONS

Mr. **Whitten**. Last year, Dr. Gramm, you indicated that CFTC was seeking legislative authority to conduct investigations of violations of foreign law upon the request of foreign futures authority. Do either the House or the Senate reauthorization bills for CFTC contain this authority?

Dr. **Gramm**. Both pending bills would provide such authority. The relevant provisions are Sections 301 through 306 of the House bill, and Sections 701 through 707 of the Senate bill. Unlike the House bill, the Senate bill does not include a provision protecting from public disclosure information received by the Commission from foreign regulators. The Commission hopes that such a provision will be included in final legislation by the conference committee.

AUTHORITY TO OPERATE

Mr. Whitten. Since reauthorization for CFTC has not been completed yet, under what authority are you continuing to operate?

Dr. Gramm. Funds for the continued administration of the Commodity Exchange Act were included in H.R. 2883, making appropriations for the Rural Development, Agriculture and Related Agencies Programs for FY 1990, which became law on November 21, 1989.

COMPUTER UPGRADE

Mr. Whitten. In November 1989, CFTC responded to a GAO report entitled "Automation Can Enhance Detection of Trade Abuses, But Introduces New Risks." Is the $2 million fiscal year 1990 supplemental request you have for ADP computer hardware related to the GAO report?

Dr. Gramm. No. The need for the $2 million enhancement of the Commission's computer capabilities was initially documented in the Commission's FY 1989 Five-Year IRM Plan which was published prior to the GAO report.

VOLUME OF TRADING

Mr. Whitten. The volume of futures trading doubled every three to five years between 1975 and 1987. Last year you informed us that, after the October 1987 market crash, while the volume continued to rise, it was at a much lower rate. Please update us on the use of commodity trading volume for the past year.

Dr. Gramm. I will provide a table that shows the annual volume of trading and percentage increases in these figures in commodity futures and commodity option contracts from FY 1975 to FY 1989. The volume of futures trading during FY 1989 increased 10.8 percent relative to volume during the previous year.

[The information follows:]

FUTURES CONTRACTS TRADING VOLUME [1975 through 1989]

	Volume of trading (thousand contracts)	Yearly percentage change
Fiscal years:		
1975	26,283.9	
1976	33,990.6	29.4
1977	41,022.8	20.7
1978	53,222.3	29.8
1979	74,309.2	39.7
1980	82,691.2	11.3
1981	101,124.3	22.3
1982	107,644.0	6.5
1983	136,077.0	26.5
1984	148,822.2	9.4
1985	152,589.7	2.6
1986	183,098.1	20.0

FUTURES CONTRACTS TRADING VOLUME [1975 through 1989]—Continued

	Volume of trading (thousand contracts)	Yearly percentage change
1987	213,546.9	16.7
1988	241,760.8	13.3
1989	267,658.4	10.8

OPTIONS CONTRACTS TRADING VOLUME

[1983 through 1989]

	Volume of trading (thousand contracts)	Yearly percentage change
Fiscal years:		
1983	1,876.8	
1984	7,953.5	323.8
1985	16,866.9	112.1
1986	30,459.6	80.6
1987	41,002.5	34.6
1988	49,029.2	19.6
1989	44,241.6	−9.8

AUDIT TRAIL SYSTEMS

Mr. WHITTEN. In the past several years, several Members of Congress have been critical of your policy to allow certain exchanges to stamp trades on a 30-minute period instead of to the minute. You recently concluded a two-year review of the Audit Trail Systems to implement the minute stamped trading and found that several exchanges still need to improve their use of trade timing information for accuracy and verifiability. Please describe some of the difficulties you found in exchanges trade timing practices.

Dr. GRAMM. In January 1986, the Commission published amendments to its Regulation 1.35 requiring that contract markets obtain a time of execution to the nearest minute for each transaction. All exchanges, except one, implemented audit trail systems intended to meet that standard by July 1987, and the remaining exchange did so in January 1988. The exchanges chose different methods to comply with the one-minute timing standard. The Chicago Board of Trade, Chicago Mercantile Exchange, and Coffee, Sugar & Cocoa Exchanges developed computerized methods using iterative processes to impute a time of execution to the minute for each trade based on specific timing and other audit trail data. The other exchanges, except for the New York Mercantile Exchange, elected to require members to record manually the actual time of execution for each transaction to the nearest minute on their record of trade execution. The New York Mercantile Exchange employs a system which provides for the timestamping of trades to the nearest minute by an Exchange employee.

The staff recently completed its initial reviews of each of the exchanges' audit trail systems. They found that each exchange generally has developed an adequate audit trail system initially to meet the one-minute performance standard established by Commission

Regulation 1.35. In its public reports on these systems, the staff has, however, recommended various enhancements. For instance, at the Chicago Mercantile Exchange and the Chicago Board of Trade, the staff recommended that the exchanges develop methods to reduce errors in the data from which trade execution times are imputed, specifically with respect to trades for other members on the floor, so-called Customer Type Indicator 3 trades, and for spread transactions. The staff also emphasized the need for maintaining a high level of verifiable accuracy for local-to-local trades and improving the computer logic. Toward that end, the CBT committed one million dollars to automated surveillance improvements. In addition, measures to reduce the potential for alteration or fabrication of timing and other data were recommended. In this regard, the Commission recently published amendments to Commission Regulation 1.35 which require, among other things, more frequent collection of trading cards and other tickets, timestamping of trading cards, the use of pre-printed sequentially-numbered trading cards, and the chronological recording of trades in non-erasable ink, without skipping lines.

With regard to hand-recordation audit trail systems, the staff's recommendations have focused on the enhancement of methods for verifying trade execution times and on continued improvement in timing accuracy. The accuracy of hand-recorded times, for example, can be assessed by comparing them to the time and price data gathered daily by an exchange and compiled in its time and sales reports and through comparisons to the time submitted by the member on the opposite side of the trade. The staff recommended generally that exchanges make more effective use of such data comparisons on a regular basis to assess the accuracy of times being submitted.

DUAL TRADING

Mr. **Whitten**. Recently, you proposed rules which would restrict dual trading. For the record, please provide a copy of the proposed rules and briefly describe their intent.

Dr. **Gramm**. Proposed Regulation 155.5 was published in the Federal Register on January 11, 1990. The notice provided for a 90-day comment period.

The proposed regulation is intended to promote the integrity of futures markets by inhibiting possible illegal conduct resulting from the ability to trade in two capacities. Specifically, the proposed regulation would make it more difficult for floor brokers to abuse their fiduciary responsibilities with regard to customer orders. The Commission believes that restricting dual trading not only should render certain abuses more difficult to commit, but also should improve the ability of contract markets to meet their compliance and surveillance responsibilities. Public confidence in the integrity of the markets is necessary if the futures exchanges are to fulfill their price discovery and hedging functions.

Proposed Regulation 155.5 would prohibit a floor broker, during any trading session in which he held or executed a customer order, from trading in the same commodity for the broker's personal account, an account over which he had trading discretion, or an account in which his ownership interest or share in profits was ten percent or more. The proposed regulation would be phased in on an incremental basis in accordance with a 12-month Implementation Plan. The Commission believes that it is prudent to obtain additional data resulting from the actual application of the proposed dual trading restriction before applying the restriction to other markets. For that purpose, the restriction initially would apply to a limited number of high-volume commodities contracts under circumstances that would affect both high- and low-volume contract markets and contract months within those commodities. During the 12-month Implementation Plan, the Commission would continue to collect and analyze data on the effect of the restriction and to expand and refine its examination of historical data.

[CLERK'S NOTE.—The information provided was too lengthy to reprint and will be maintained in Committee files.]

SWAP TRANSACTIONS

Mr. WHITTEN. For the record, please describe "swap transactions."

Dr. GRAMM. In general, a swap may be characterized as an agreement between two principals to exchange a series of cash flows measured by different interest rates, exchange rates, or prices, with payments calculated by reference to a principal base, or notional amount. Interest rate swaps are the most common and highly developed swap product and are used for many purposes. Typically an interest rate swap involves the "swapping" of a fixed rate obligation for a floating rate obligation, or vice versa, to more closely match movements in the value of the assets and liabilities of the parties to the swap. Swaps are transacted in global markets dominated by large commercial and institutional participants engaging in privately negotiated, typically long-term, credit-based trades.

FOREIGN MARKET OVERSIGHT

Mr. WHITTEN. In fiscal year 1989, the Commission approved applications from foreign futures and options exchanges to offer and sell various option contracts in the United States. Since the Commission relies significantly on self-regulation, describe for us your oversight responsibility as related to foreign exchanges.

Dr. GRAMM. The Commission does not have oversight responsibility with respect to foreign markets comparable to that which exists with respect to domestic contract markets. The Commodity Exchange Act provides that in adopting rules and regulations governing futures transactions on foreign markets for or on behalf of persons resident in the United States, the Commission may not adopt rules which would in any way require Commission approval of any contract, rule or action of a foreign market or its clearing house or govern in any way any rule or contract term or action of any foreign exchange or its clearing house. Thus, in directing the Commission to regulate the foreign futures activities of United States residents, Congress did not intend that the Commission acquire regulatory authority with respect to foreign markets of foreign clearing houses.

Similarly, notwithstanding the Commission's plenary authority with respect to options, the Commission does not regulate foreign option contracts in the same manner in which domestic option products are regulated. For example, foreign exchanges offering such contracts are not required to be designated. Rather, in determining whether to lift the options ban with respect to a particular foreign market, the Commission considers the availability of information relevant to preventing abuses in the trading of such option contracts, including information sharing arrangements with the relevant regulatory authorities; the arrangements in place for assuring that sales practice abuses in such options do not occur, including undertakings by the appropriate foreign entity for the fulfillment of sales practice compliance obligations in effect in the foreign jurisdiction; and arrangements for United States customers to redress grievances with respect to their option transactions on that market. Specifically, the Commission relies on information sharing arrangements in recognition of the fact that the regulatory authority in the jurisdiction in which the market is located is in the best position to monitor the market for compliance with rules applicable to such market.

DUAL TRADING EXCEPTIONS

Mr. WHITTEN. The proposed dual trading prohibition is subject to certain exceptions deemed permissible by the Commission. Please describe these exceptions.

Dr. GRAMM. An exchange would be permitted to adopt any or all of three specified exceptions to proposed Regulation 155.5's dual trading restriction by adopting implementing rules. For each such exceptions, the proposed regulation would establish minimum requirements.

Under the first proposed exception, if an exchange maintained trading records that differentiated brokerage activity between exchange members and public customers, the exchange could distinguish between member and public customers for purposes of the proposed dual trading restriction. A floor broker who was a member of that exchange could trade as a principal during the same session in which he held or executed orders in the same commodity for any other member, including one not present on the floor. In proposing this exception, the Commission is recognizing that the primary purpose of restricting dual trading is to protect public customers and that members are better able than public customers to monitor the manner in which their orders are handled.

Under the second proposed exception, an exchange could adopt rules pursuant to which a customer could consent to receiving brokerage services from a floor broker during the same trading session in which that broker was trading in the same commodity as principal. For such consent to be effective, it would have to be in writing, identify the broker by name, and have been executed within the previous twelve months. In proposing this exception, the Commission is recognizing that any customer, including a public customer, who is aware of the risks associated with dual trading should be free to maintain business relationships with dual-trading brokers.

Under the third proposed exception, an exchange could allow a floor broker to place trades executed to fill customer orders which resulted in errors into the broker's personal error account. However, the exchange would be required to limit the period of time for which a broker could hold a position in an error account so as to reduce the potential use of that account for personal trading. Specifically, a floor broker would have to liquidate a position resulting from an error discovered during a trading session as soon as possible during that session and an error discovered after the end of a trading session at the opening of the next session. In proposing this exception, the Commission is recognizing that errors may occur, in the order execution process, while ensuring that error accounts are not used to accomplish abuses otherwise precluded by the Act and regulations.

REAUTHORIZATION RESOURCES

Mr. WHITTEN. Fiscal year 1989 was supposed to be the reauthorization year for the Commodity Futures Trading Commission. That task is yet uncompleted. The resources associated with the reauthorization used by CFTC are usually extensive. For the record, please provide a five year history of resources of the Office of Congressional and Governmental Affairs.

Dr. GRAMM. Each year, the Commission devotes two full-time staff-years to support the activities of the Office of Congressional and Governmental Affairs. Over the past five years, agency staff has contributed nearly 5 staff-years of effort to the reauthorization process, at a cost of approximately $300,000.

INVESTIGATIONS

Mr. WHITTEN. For the record, please provide a table showing the number of investigations in the Division of Enforcement for the past five years.

Dr. GRAMM. I would be pleased to provide information on the number of Enforcement investigations.

[The information follows:]

ENFORCEMENT INVESTIGATIONS [1986 through 1989]

	Pending at beginning of fiscal year	Opened during	Closed during
Fiscal year:			
1986	139	70	86
1987	123	57	80
1988	100	80	71
1989	109	89	68
1990	130	[1] 23	[1] 16

[1] Through February 1990.

INTRODUCING BROKERS

Mr. WHITTEN. For the record, please provide a table showing the numbers of registered introducing brokers since the 1982 amendments to the CFTC Act.

Dr. **Gramm**. The registration requirements for introducing brokers became effective in fiscal year 1983. The number of registrants at the end of each fiscal year is provided for the record.

[The information follows:]

Fiscal year:	*Number of introducing brokers*
1983	591
1984	635
1985	991
1986	1,247
1987	1,517
1988	1,673
1989	1,774

ADMINISTRATIVE PROCEEDINGS AND INJUNCTIVE ACTIONS

Mr. **Whitten**. Please provide a listing of all administrative proceedings instituted in fiscal years 1988 and 1989, and all injunctive actions instituted in fiscal years 1988 and 1989.

Dr. **Gramm**. I would be pleased to provide that information.

[**Clerk's note**.—The information provided was too lengthy to reprint and will be retained in committee files.]

FUTURES AND OPTIONS CONTRACTS

Mr. **Whitten**. For the record, please provide a table showing all futures and options contracts approved and traded during fiscal year 1989. Also provide the volume of each that was traded during the year.

Dr. **Gramm**. I will provide a table that shows all futures and options contracts approved and traded during fiscal year 1989 and the volume of each that was traded during the year.

[The information follows:]

FUTURES AND OPTION DESIGNATIONS OF CONTRACT MARKETS IN FISCAL YEAR 1989 THAT WERE TRADED IN FISCAL YEAR 1989

Exchange	Contract	Date of commission approval	Fiscal year 1989 volume (in contracts)
CME	Japanese yen Euro-rate—differential futures	/29/89	6,247
CME	British pound Euro-rate—differential futures	/29/89	7,467
CME	Deutschemark Euro-rate—differential futures	5/29/89	9,343
NYCE	Two-year U.S. Treasury—note futures	2/13/89	106,783

AGRICULTURAL TRADING VOLUME

Mr. **Whitten**. Of the total volume of trading in futures and options contracts for the last ten years, what percent is for agricultural commodities? Also, please provide a list of these agricultural commodities.

Dr. **Gramm**. I will provide for the record a table that shows the percentage of futures and options contracts traded that were classified as traded on domestic agricultural commodities. Although volume of trading in domestic agricultural contracts during 1989 was approximately the same as in 1980, the share of trading in these commodities relative to total trading volume fell from 58.4 percent in 1980 to 17.5 percent in 1989 due to the growth of trading in nondomestic agricultural futures.

[The information follows:]

VOLUME IN DOMESTIC AGRICULTURAL [1] (AG) CONTRACTS AS A PERCENT OF TOTAL FUTURES VOLUME

Fiscal year	Futures			Options		
	Domestic Ag contracts	Total volume	Ag as a percent of total	Domestic Ag contracts	Total volume	Ag as a percent of total
1980	48.3	82.7	58.4			
1981	51.5	101.1	51.0			
1982	42.9	107.6	39.9			
1983	50.2	136.1	36.9	0	1.9	0
1984	49.1	148.8	33.0	0	8.0	0
1985	34.2	152.6	22.4	1.2	16.9	7.2
1986	33.6	183.1	18.3	2.3	30.5	7.5
1987	35.2	213.5	16.5	3.4	41.0	8.2
1988	49.3	241.8	20.4	6.6	49.0	13.4
1989	46.8	267.7	17.5	6.1	44.2	13.9

[1] Domestic agricultural commodities: Wheat, corn, oats, rice, soybeans, soybean oil, soybean meal, cotton, live hogs, live cattle, feeder cattle, and pork bellies.

INSPECTOR GENERAL

Mr. WHITTEN. Recently, you established the position of Inspector General at CFTC. Her first semiannual report provided an agenda of actions to be taken. Does the Inspector General have authority to conduct criminal investigations? Will the IG have authority to review exchanges' actions or will it be restricted to reviewing CFTC activities?

Dr. GRAMM. The Inspector General does not have the authority to conduct criminal investigations; however, to the extent the investigation may pertain to a criminal violation of Federal law, the IG must report the case to the Attorney General. The Inspector General has access to all records, reports, audits, reviews, documents, papers, recommendations, or other material available to the Commission and has responsibility to conduct any necessary investigations of the administration or operation of its programs and operations.

The Inspector General will evaluate the efficiency and effectiveness of all aspects of the CFTC programs and operations. In some cases, such an evaluation of CFTC operations may require a review of exchange actions as well. For example, as I recall, the first agenda indicated an intention to evaluate the CFTC exchange review program. This may require review of exchange actions in order to assess the effectiveness and efficiency of the CFTC review program.

MEMORANDUM OF UNDERSTANDING

Mr. WHITTEN. For sometime now, CFTC has been working on bilateral agreements with foreign futures regulators. Recently, you came to an agreement with the United Kingdom. Please describe for us the content of this agreement.

Dr. GRAMM. The Memorandum of Understanding between the Department of Trade and Industry, the Securities and Exchange Commission and the Commodity Futures Trading Commission, was signed on September 23, 1986, with a supplemental Memorandum signed on November 22, 1988, that added the Securities and Investments Board as a signatory to the agreement. On May 15, 1989, the agreement was broadened between the Commission and the Board. Under that arrangement, the Commission has access to information from the Bank of England and certain United Kingdom self-regulatory organizations, such as the Association of Futures Brokers and Dealers. The broadened agreement provides for the sharing of monitoring and surveillance information for United Kingdom firms granted comparability relief by the Commission.

Also on May 15, 1989, the Commission, the Securities and Investments Board and certain United States and United Kingdom self-regulatory organizations entered into an addendum to the Financial Information Sharing Memorandum of Understanding. This arrangement provides for sharing of financial information on a routine and on an as needed basis with respect to firms in the United Kingdom granted comparability relief. This addendum supplements the Financial Information Sharing Memorandum of Understanding originally entered into on September 1, 1988, which provides for similar information sharing with respect to firms in the United States granted relief from certain United Kingdom capital requirements.

FIRM FAILURES

Mr. WHITTEN. How many firms trading in the futures and options markets failed during the past year?

Dr. GRAMM. Since December 1988, two small firms have failed. In December 1988, X-Cel Commodities Corp., failed, losing approximately $230,000 of customer funds. In September 1989, Inter-Brokers USA Inc., failed, losing approximately $2.6 million of foreign customers' funds. Neither firm was a clearing member of a contract market.

Drexel Burnham Lambert, Inc., a futures commission merchant, and a securities broker/dealer, has recently ceased doing business because its parent company, Drexel Burnham Lambert Group, Inc. filed for bankruptcy. This was not a failure of a futures commission merchant, but it is mentioned here, because it may be perceived as such by the public. In fact, Drexel Burnham Lambert was always, and still is, in compliance with regulatory capital and segregation requirements.

MARKET PARTICIPATION

Mr. WHITTEN. Dr. Gramm, in 1989 you indicated that the Commission routinely collects information regarding positions of large traders in all actively traded futures and options markets and, to the extent that farmers fall into this category of traders, their positions are actively monitored. Do you have any more recent data on the extent to which markets are used by farmers than in the livestock survey conducted in March 1987?

Dr. GRAMM. While we have not done a more recent market-wide survey to measure the extent of farmer participation in futures and option markets, we continue to receive daily reports of the positions of all large traders. Those reports reveal, for example, that all reportable agricultural commercial traders held an average of 35 percent of the total long open interest and 45 percent of the total short interest. Reportable commercial cattle traders held about 17 percent of the long and 35 percent of the short open interest in live cattle futures at the end of February 1990. Cattle feeders are prominent among those large commercial users of cattle futures. Market participation data by small nonreporting traders require special surveys of all accounts at the brokerage firms and, therefore, are very resource-intensive. For instance, after initial screening of all registered futures commission merchants, the 1987 livestock survey required collection of information on over 25,000 separate accounts carried by 129 futures commission merchants and clearing members. Even with the use of electronically readable data, this involves a considerable effort to ensure correct account classification. Accordingly, the Commission limits these surveys to those circumstances where the need for the information justifies the expense to the government and the industry.

AGRICULTURAL OPTIONS

Mr. WHITTEN. Please provide for the record a list of all the agricultural option contracts that are now being traded.

Dr. GRAMM. I will provide for the record a table that shows all agricultural option contracts now being traded.

[The information follows:]

AGRICULTURAL OPTION CONTRACTS BEING TRADED

[As of February 28, 1990]

Exchange	Contract
CBT	Soybeans.
	Soybean oil.
	Soybean meal.
	Corn.
	Wheat.
CME	Live hogs.
	Live cattle.
	Pork bellies.
	Feeder cattle.
KCBT	Wheat.
MACE	Wheat.
	Soybeans.
MGE	Spring wheat (American exercise).
	Spring wheat (European exercise).
NYCE	Cotton.

CONTRACTS TRADED

Mr. WHITTEN. Please provide for the record a table showing annual volume of futures trading in the past five years and contracts traded on domestic agricultural commodities and contracts traded on nonagricultural commodities.

Dr. **Gramm**. I will provide for the record a table that shows the information requested. The group of contracts denoted as "other" contains foreign agricultural commodities such as cocoa, coffee, and sugar, as well as nonagricultural commodities.

[The information follows:]

NUMBER OF CONTRACTS TRADED FOR DOMESTIC AGRICULTURALS AND OTHERS FISCAL YEAR 1985 THROUGH FISCAL YEAR 1989

	Domestic agricultural commodities traded	Other commodities traded	Total contracts traded (both groups)
Fiscal year:			
1985	34,212,156	118,377,497	152,589,653
1986	33,561,291	149,536,785	183,098,076
1987	35,172,498	178,374,356	213,546,854
1988	49,340,155	192,420,600	241,760,755
1989	46,757,044	220,901,346	267,658,390

40-COUNTY PILOT PROGRAM

Mr. **Whitten**. Dr. Gramm, the 1985 Food Security Act approved a 40-county pilot agricultural options program. Last year, you testified that the majority of experience related to this pilot program was negative. Did you continue the program through fiscal year 1989 and do you have any plans for activity during fiscal year 1990?

Dr. **Gramm**. The CFTC acted in a consulting role on the 40-county pilot program. USDA had the main responsibility for the pilot program, with the Agricultural Stabilization and Conservation Service responsible for implementing the program. CFTC staff worked with the USDA Extension Service on the educational program to advise producers on the nature of options and the regulatory role played by the CFTC. Staff also served on an evaluation committee and participated in a seminar conducted by the USDA's Economic Research Service. USDA had all of the operational and financial responsibility for the pilot program. Our understanding is that the pilot program was continued for fiscal year 1989. We are continuing our contacts with USDA as they explore further work in this area.

Mr. **Whitten**. What are the total costs related to the 40-county pilot program that the CFTC has expended to date?

Dr. **Gramm**. The 40-county pilot program was administered by the U.S. Department of Agriculture. The CFTC's role was primarily as a consultant to USDA at its request. The CFTC's costs relating to the entire program to date are less than $10,000.

NFA ACTIONS

Mr. **Whitten**. For the record please provide a table showing information for sales practice and financial related disciplinary actions taken by the National Futures Association during calendar years 1988 and 1989.

Dr. **Gramm**. I will supply a table which indicates fines, suspensions, and expulsions levied by the National Futures Association in 1988 and 1989. We will also show the number of complaints issued divided into sales practice and financial cases.

[The information follows:]

DISCIPLINARY ACTIONS TAKEN BY THE NATIONAL FUTURES ASSOCIATION 1988 - 1989

YEAR	FINES INVOLVING SALES PRACTICE CASES	FINES INVOLVING FINANCIAL CASES	TOTAL FINES LEVIED BY NFA BCC DECISION	EXPULSIONS INVOLVING SALES PRACTICE CASES	EXPULSIONS INVOLVING FINANCIAL CASES	TOTAL EXPULSIONS ORDERED BY NFA BCC DECISION	SUSPENSIONS INVOLVING SALES PRACTICE CASES	SUSPENSIONS INVOLVING FINANCIAL CASES	TOTAL SUSPENSIONS ORDERED BY NFA BCC DECISION	NUMBER OF NFA SALES PRACTICE COMPLAINTS	NUMBER OF NFA FINANCIAL COMPLAINTS	TOTAL NUMBER OF NFA COMPLAINTS
1988	$597,975	121,500	719,475	19	2	21	24	2	26	31	10	41
1989	345,000	65,000	410,000	19	2	21	34	6	40	25	11	36
TOTAL:	$942,975	186,900	$1,129,475	38	4	42	58	8	66	56	21	77

16-YEAR TRADING HISTORY

Mr. **Whitten**. Last year, Dr. Gramm, you provided a table that appears on page 68 of the hearing record which shows the trade volume for basic agricultural commodities for the past 15 years. Please update that table and also provide an additional column that shows total volume of nonagricultural trades.

Dr. **Gramm**. I will provide a table that updates the table on volume of contracts traded for the past 15 years. "Other" commodities will include foreign agricultural as well as all nonagricultural commodities.

[The information follows:]

TABLE FOR 16 YEARS SHOWING VOLUME OF TRADING FOR DOMESTIC AGRICULTURAL AND FOR OTHER COMMODITIES

	Total agriculturals	Other nonagriculturals	Total volume for all contracts
Fiscal year:			
1974	17,054,126	7,959,351	25,013,477
1975	18,480,139	7,803,795	26,283,934
1976	22,708,838	11,281,735	33,990,573
1977	27,938,370	13,084,455	41,022,825
1978	33,714,195	19,508,126	53,222,321
1979	42,671,532	31,637,707	74,309,239
1980	48,259,082	34,432,087	82,691,169
1981	51,536,203	49,588,093	101,124,296
1982	42,920,292	64,723,727	107,644,019
1983	50,165,558	85,911,491	136,077,049
1984	49,075,451	99,746,783	148,822,234
1985	34,212,156	118,377,497	152,589,653
1986	33,561,291	149,536,785	183,098,076
1987	35,172,498	178,374,356	213,546,854
1988	49,340,155	192,420,600	241,760,755
1989	46,757,044	220,901,346	267,658,390

COMMODITIES TRADED 1955 VERSUS 1989

Mr. **Whitten**. For the record, please provide a listing of all commodities traded in 1955 and a listing of all commodities traded in 1989.

Dr. **Gramm**. I will provide a table which shows a listing of all commodities traded during 1955 and 1989.

[The information follows:]

COMMODITIES TRADED IN 1955 AND 1989

Commodity	Year Traded 1955	Year Traded 1989
Domestic Agricultural		
Wheat	X	X
Corn	X	X
Oats	X	X
Rye	X	
Grain Sorghums	X	X
Soybeans	X	X
Soybean Oil	X	X
Soybean Meal	X	X
Cotton	X	X
Cottonseed Oil	X	
Bran	X	
Shorts	X	
Middling	X	
Flaxseed	X	
Butter	X	
Eggs	X	
Potatoes	X	
Onions	X	
Rice		X
Hogs		X
Cattle		X
Feeder Cattle		X
Pork Bellies		X
Corn Syrup		X
Other Agricultural		
Wool	X	
Wool Tops	X	
Cocoa	X	X
Coffee	X	X
Sugar	X	X
Orange Juice		X
Precious Metals		
Platinum	X	X
Silver		X
Gold		X

Commodity	Year Traded 1955	Year Traded 1989
Industrial		
Hides	X	
Rubber	X	
Copper	X	X
Lead	X	
Tin	X	
Zinc	X	
Burlap	X	
Silk	X	
Lumber		X
Heating Oil		X
Crude Oil		X
Gasoline		X
Propane		X
Aluminum		X
Palladium		X
Financials, Foreign Currencies and Indices		
Treasury Bonds		X
Treasury Notes (6-1/2 - 10 Yr)		X
Treasury Notes (5 Yr)		X
Treasury Bills		X
30-Day Rates		X
Municipal Bonds		X
GNMA Mortgages		X
Eurodollars		X
Euro-Mark Differential Rate		X
Euro-Pound Differential Rate		X
Euro-Yen Differential Rate		X
Foreign Currency		X
Dollar Index		X
European Currency Unit		X
CPI Index		X
CRB Index		X
Int'l Market Index		X
Stock Market Indices		X

Mr. WHITTEN. Mrs. Smith?

Mrs. SMITH. Thank you, Mr. Chairman.

Welcome, Commissioner Gramm, and welcome to your associates, too.

I would like to talk a little bit more and ask you a question or two about my understanding that the Treasury Department and the SEC are arguing that SEC should regulate the stock index futures.

Now, if oversight of the stock index futures were transferred to the SEC, would that have an impact on CFTC's oversight of agricultural markets?

Dr. GRAMM. It certainly would. The agency would be weakened in our ability to oversee the agricultural markets, and the staff would be weakened, as well. That is part of our concern.

Mrs. SMITH. I understand that the reauthorization bill is stalled in the Senate because of a jurisdictional dispute. Now, Commissioner Gramm, wouldn't it be wise to separate these issues and allow much-needed future market reforms to move ahead?

Dr. GRAMM. I agree with that wholeheartedly. We need the authorities that are in our reauthorization package. Both bills are strong bills and give us a lot of authorities not only to monitor the markets, but also to keep up with, for example, what is going on in the international sphere, as well.

DIRECT OVERSIGHT

Mrs. SMITH. Now, has the Commission taken steps in the last year to increase its direct regulatory oversight over the exchanges?

Dr. GRAMM. Yes, we have. We have increased our floor surveillance. We have written rules to enhance the audit trail system, in particular, making it more difficult for traders to alter the trading cards. We are requiring that the trading cards be collected more often. We have written rules that would bar members who have a disciplinary history from serving on arbitration panels or on disciplinary committees of the exchanges. We have proposed a ban on dual trading. We have a number of things that we are in the process of doing and a number of things that we have already completed, as well.

Mrs. SMITH. I know that you are asking for a 21 percent increase in your budget, and that, of course, is a significant increase. Could you explain just a little bit more about why you feel this is badly needed?

Dr. GRAMM. Well, the 21 percent increase can be broken out to a 15 percent real increase in resources, and 6 percent would just basically be the inflation for current services.

The primary reason that we are asking for the additional resources is for a computer upgrade but, more importantly, for our floor surveillance and our enforcement efforts—especially in the trade practice area—to increase our ability to monitor trade practices and bring cases against those who would violate the law.

Mrs. SMITH. Thank you again. We are glad you are here.

That's all, Mr. Chairman.

Mr. WHITTEN. Mr. Smith?

Mr. **Smith**. Did I understand you to say that it would weaken the CFTC's ability to handle agricultural commodity futures if a decision is made to split out those financial futures relating to stocks and put that under the SEC?

Dr. **Gramm**. My concern is it would weaken the agency and the staff. We would lose staff. The question is whether or not we would have a critical mass of expertise to monitor agricultural futures if a large number were to transfer to the new agency.

Mr. **Smith**. Why would you lose staff? It seems to me that if you lost jurisdiction over those contracts then you could do a better job of administering the contracts you had left.

Dr. **Gramm**. In actual fact, as you can see, even though the contract volume has gone up and we have new contracts, we have a certain core staff that monitors, for example, stock index futures the same way essentially that we monitor cattle futures. That staff is applied across all futures. So it is not so easy to just say these are the 80 people or the 25 people or however many that monitor stock index futures.

Mr. **Smith**. But wouldn't they have more time to provide closer surveillance on the contracts you have left?

Dr. **Gramm**. They may have. But, indeed, the question is one of how much expertise is left in the agency, as well.

NUMBER OF CONTRACTS

Mr. **Smith**. Well, how many contracts do you have at the present time?

Dr. **Gramm**. We have over 100 active contracts trading. We have 81 futures and about 40 option contracts that we are monitoring.

Mr. **Smith**. And how many contracts are we talking about that would be split out if you were to split out the ones that relate to stocks, options, and stock index futures?

Dr. **Gramm**. There are four stock index futures. The SEC has jurisdiction over stock index options.

Mr. **Smith**. Just four contracts?

Dr. **Gramm**. And, as a matter of fact, for stock index futures the largest one is the S & P 500.

Mr. **Smith**. Yes. You also have some other financial contracts though?

Dr. **Gramm**. Yes. As a matter of fact, of the 81 active futures contracts, 27 of them—one-third—are agriculture, 35 are financial, and 19 are other commodities like metals.

Mr. **Smith**. Well, the other commodities are not really in controversy, are they? I mean, I know they are to some extent because some people want to close out CFTC altogether.

Dr. **Gramm**. That's right.

Mr. **Smith**. But of those that don't want to close out CFTC altogether, they are not recommending that all financial futures should go to SEC?

Dr. **Gramm**. There are a number of proposals that I have heard, and they vary from a complete merger to a transfer of stock index futures or perhaps stock index futures and all financials.

PRESIDENTIAL WORKING GROUP

Mr. **Smith**. Well, you are on a working group—I don't know what you call it, but some kind of a working group.

Dr. **Gramm**. That's right.

Mr. **Smith**. Four people are on that?

Dr. **Gramm**. That's right.

Mr. **Smith**. Cabinet level. What do you call it?

Dr. **Gramm**. This is the Presidential Working Group on Financial Markets. It is chaired by Treasury Secretary Brady's designee.

Mr. **Smith**. What is the jurisdiction? What are you to come up with? What kind of conclusions?

Dr. **Gramm**. The working group is discussing jurisdictional issues at this time but has not come up with a conclusion.

Mr. **Smith**. Then would it be discussing whether or not to change the arrangement that was made between Johnson and Shad, or does it go further than that?

Dr. **Gramm**. There are a wide range of proposals including merger.

Mr. **Smith**. So it could include merger?

Dr. **Gramm**. Yes.

Mr. **Smith**. When do you think there will be a decision?

Dr. **Gramm**. That is hard for me to predict.

Mr. **Smith**. Is it imminent, though? Is it in time to affect the authorization that is in the Senate?

Dr. **Gramm**. I think if we waited for jurisdictional issues to be resolved our reauthorization would be held up far too long.

Mr. **Smith**. I see.

Dr. **Gramm**. But it is hard for me to predict.

PENSION FUNDS

Mr. **Smith**. We have got to go here in just a minute so I will cut short my questions. But I do have one question that I think is important. What affect do pension funds currently have on futures markets?

Dr. **Gramm**. Pension funds have been large users of stock index futures and other futures as hedging mechanisms—as a hedging device.

Mr. **Smith**. Do they use them more in connection with their operations on the stock exchange? Is that it?

Dr. **Gramm**. That's right.

Mr. **Smith**. Looking for which place they can get the best deal?

Dr. **Gramm**. That's right. An example is this: a pension fund, for example, may get a large amount of money every month from the people who contribute—$100 million. They know they are going to be putting that into bonds or the stock market. And so like a cattle farmer or a cotton farmer, they may hedge the price and then buy their portfolio stocks or their Treasury bills or whatever assets they are going to buy over a period of time, and their price risk is hedged.

Mr. **Smith**. They are getting to be a major factor in all of the markets, then? That is what it amounts to.

Dr. **Gramm**. That's right.

Mr. **Whitten**. I guess we had better go vote and come back. Excuse us. We will be right back.

Dr. **Gramm**. Okay.

[Recess.]

Mr. **Whitten**. Mr. Skeen?

STOCK INDEX FUTURES

Mr. **Skeen**. Thank you, Mr. Chairman.

Ms. Commissioner and folks, it is good to have you here.

We started talking about the situation of transfer of the CFTC's jurisdiction on the stock index futures to the SEC, and I think you made it pretty clear what your opinion is on that.

Let me carry this just a little bit further. What indication do you get from the Treasury Department or the SEC on what changes they would make or propose to the current regulations of stock index futures if they were given some of this responsibility?

Dr. **Gramm**. I would be interested in more details about that myself. My concern is that, based on SEC's previous opposition to stock index futures and, more recently, statements about increasing margins to at least 20 percent that indeed stock index futures could face a rather hostile regulatory environment if jurisdiction were transferred, and that could increase the cost to users of some of these instruments and thereby harm the competitive position.

Mr. **Skeen**. So cost is one factor?

Dr. **Gramm**. Cost is one factor, and other regulatory restrictions.

Mr. **Skeen**. Have they been very open about this or has it been just more in the area of speculation?

Dr. **Gramm**. I don't think anybody has been really explicit about what would be done differently if stock—

Mr. **Skeen**. It comes under the category "what if."

Dr. **Gramm**. That's right.

INTERNATIONAL COMPETITIVENESS

Mr. **Skeen**. Let me ask you about the impact a jurisdictional transfer would have on international competitiveness of the U.S. stock index futures products.

Dr. **Gramm**. That is an area of real concern. I think it is important that we do what is best for the economy.

Under the current regulatory regime we have become the world leader in terms of innovation. We have the oldest markets, the largest, the most liquid. So the real question is: what would be the benefits of any change?

My concern is that we could jeopardize our international leadership position in this area—in the financial futures area—if stock index futures jurisdiction were transferred over to the SEC. We are in a leadership position now, and that could be jeopardized by a change.

REGULATORY INNOVATION

Mr. **Skeen**. You mentioned innovation, and the Chairman of the SEC and the Secretary of the Treasury have mentioned that one of their problems with it is they feel the current regulatory structure stifles innovation. You mentioned innovation. Give me some innovative ideas that CFTC has come up with.

Dr. **Gramm**. The agency has a long record of encouraging innovation and being supportive of innovation over its history. Not only the development of financial futures—which were developed and supported by this agency and by this industry, but also more recently—in the last year to year and a half—we have approved Globex in its initial stages, which would be an innovative screen trading system for futures products. Amex Commodities Corporation has another trading system, and the CBT has a third screen trading system that they have proposed for approval. We have approved a number of new contracts over the past year. So there are a number of innovations.

Furthermore, in the area of new kinds of financial products that are valuable to firms and institutions that are trying to hedge against price risk, we have done a number of things the past year in writing rules to further clarify the regulatory treatment of these new products which would allow a lot of innovation in that particular area.

Mr. **Skeen**. There is a lot of discussion that the original idea with CFTC was to handle solely and strictly commodities. I know the financial futures have been an innovation, and I feel probably now it is a bigger end of the market transactions that take place under the commodities market. Am I correct?

Dr. **Gramm**. You are correct in that. As you know, the authorizing committees have defined commodity rather broadly. I point out that what we do at the agency is regulate and monitor futures and options—these risk shifting instruments. Whether or not the underlying product is an agricultural product or a metal or gold or some financial product, the way we monitor them is the same.

Mr. **Skeen**. Any raw material type of resource production.

The thing that bothers me is: suppose we decide to take just the financial futures out of your jurisdiction. If you relied on the strict definition of only agricultural commodities there would not be those markets today in my view. Is this a fairly correct assumption?

Dr. **Gramm**. That's right.

Mr. **Skeen**. Because they would not be supported. They have not in the past and probably will not in the future. So the financial futures is a very important part of this commodity picture and it could be handled. I think it has been a great advent and it has kept the commodity interest in trade in agricultural products, which brings an awful lot of income and strength and a good marketing tool to agriculture.

Dr. **Gramm**. That's right. I like to say that the large institutions and the multi-nationals and the big firms, including pension funds, have learned what farmers learned a long time ago, and that is that these instruments can be valuable in hedging the price risk that farmers faced for a long time. The farmers were the first at it.

Mr. **Skeen**. We are just now beginning to teach farmers to do a lot of that. They haven't had the money to do it in the past.

Dr. **Gramm**. That's right. Not all farmers use them, but a large number.

Mr. **Skeen**. But it is a marketing tool, and it is one that is there. I think as agriculture advances—as it inevitably has to do—through technology, it is going to play an even more important role.

I thank you for your responses.

Thank you, Mr. Chairman.

Dr. **Gramm**. Thank you.

Mr. **Whitten**. I have two tables here I want to put in the record. One reflects volume of trading differences for some basic agriculture commodities between 1980 and 1989. The other table shows some examples of trading in 1955 and more recently. I want to put these in the record to show how agriculture commodity trading has become such a small part of what you regulate.

[The information follows:]

Volume of Trading for Fiscal Years 1980 and 1989

Commodity	Contract Unit	FY 1980 Volume of Trading (Contracts)	FY 1989 Volume of Trading (Contracts)
Wheat	5,000 Bu.	6,919,185	5,208,192
Corn	5,000 Bu.	10,383,207	9,732,272
Oats	5,000 Bu.	278,289	372,610
Soybeans	5,000 Bu.	9,531,616	10,858,420
Cotton	5,000 Lbs.	2,472,650	1,546,271
Subtotal		29,584,947	27,717,765
S&P 500	$500 x Index	0	10,549,275
Treasury Bonds	$100,000	4,845,972	72,639,796
Subtotal		4,845,972	83,189,071
Total All Futures		80,946,245	267,658,390

Commodities Traded

1955

1. Wheat
2. Corn
3. Oats
4. Rye
5. Soybeans
6. Grain Sorghums
7. Cotton
8. Cottonseed Oil
9. Soybean Oil
10. Lard, Drummed
11. Lard, Loose
12. Soybean Meal
13. Bran
14. Shorts
15. Middlings
16. Barley
17. Flaxseed
18. Butter
19. Eggs
20. Potatoes
21. Onions
22. Platinum
23. Wool
24. Wool Tops
25. Tallow
26. Cottonseed Meal
27. Soybean Meal
28. Cocoa
29. Coffee "B"
30. Coffee "M"
31. Sugar #6
32. Sugar #4
33. Hides
34. Rubber
35. Copper
36. Lead
37. Tin
38. Zinc
39. Burlap
40. Silk

1987-88

All commodities traded in 1955 plus 74 additional commodities for a total of 114. Some examples of these additional commodities are:

1. U.S. Treasury Bonds
2. Eurodollars
3. GNMA (Mortgages) CDR
4. Gold
5. Palladium
6. Stock Index, Institut.
7. Cattle, Live
8. Lumber
9. Oil, Heating No. 2
10. Yen, Japanese
11. Orange Juice
12. Aluminum
13. Gasoline, Leaded
14. Gasoline, Unleaded
15. Mark, Deutsche
16. Pound Sterling
17. Potatoes

Volume of Trading

15 different exchanges had trading volume contracts of 4,107,153.

12 different exchanges had trading volume contracts of 241,760,755. In addition, 10 of the 12 exchanges had options trading volume of 49,029,200, for a total futures and options trading volume of 290,789,955.

Mr. Whitten. One thing that worries me after reading the press about all the violations in the markets is whether the markets are sound. I have been to the exchanges in Chicago two or three times and once or twice in New York. To a layman, to see all the activity that goes on is mind boggling, but to a lawyer, you begin to see all of what is happening. The fellow down in Podunk has to trust the fellow in Chicago. The point is that it has developed that we can't trust them. Now what are we going to do about that? Can you computerize trading to allow a man in south Tennessee to trade so he wouldn't have to rely on the honesty of that man or woman in Chicago? How are we going to straighten this out where you are not depending on the integrity of some trader in the pits that you don't even know?

Dr. Gramm. Mr. Chairman, a lot of what we have been doing this past year is addressing exactly what your concerns——

Mr. Whitten. The exchanges have been in business a long time, and instead of it getting cleaner they're getting worse.

Dr. Gramm. Well, all these rules that we have undertaken and are undertaking are to try——

Mr. Whitten. A rule is only worth the amount of enforcement it has.

Dr. Gramm. That's right. Exactly. And what we are asking for is not only to put in the rules, but also to enforce.

Mr. Whitten. The folks you can trust don't need any rules, and the folks that want to violate them will find out what the rule is and learn how to go around it.

Dr. Gramm. That is always the challenge.

Mr. Whitten. For instance, since 1955, 74 additional commodities such as U.S. Treasury Bonds and gold are traded. How do these additional commodities get on the exchanges? A gambler is going to find something to gamble on.

What we are talking about here is after the commodity has gotten out of the hands of the average farmer we read about the price going up or down and the farmer gets no benefit if it went sky high. I'm talking about the average farmer now, not your big corporate operators. We have tried to get them to hedge their bets. We have tried a number of things, but the more we try the worse it seems to get. Now the two committees that have jurisdiction over the exchanges can't agree on what to do.

Dr. Gramm. I don't think there is any disagreement on monitoring the floors of exchange. The Commission——

Mr. Whitten. What are you going to do to make the exchanges do right?

Dr. Gramm. We bring cases and——

Mr. Whitten. Is the computer system helping any?

Dr. Gramm. Pardon me? We work with U.S. attorneys and also with the State officials. And when we find those who are violating——

CONTRACT MARKET DESIGNATION

Mr. Whitten. Let me go back and ask you my first question. I know I have asked you a lot of questions without waiting for an answer. How do you get a commodity listed on the exchange?

Dr. Gramm. In order to get it listed, the exchange has to come to the Commission and we have to approve that contract. We will look at the specifications. We also have to look at the exchange's ability to carry out its responsibilities to monitor those products.

Mr. Whitten. We deal with agriculture on this subcommittee, and in dealing with it we have seen over 300,000 farmers go broke. We have also seen a portion of our market go to overseas competitors. I recently read a story about the Mississippi Delta—the richest land in the country about ten years ago. Now it is flat broke with just about every small town dried up.

I have been trying to get the Department of Agriculture to return to using the Commodity Credit Corporation for the purpose it was intended. The farmers should get his price from the user. I have had very little luck with this, but that is what I have been trying to do, and I think I am sound in trying to get them to do it.

What profit is it if we continue to have an open door policy and allow imports to come in freely? What good is the stock market if you can't trust the traders you call up to bid on or seil your commodity? Forty-seven indicted is a good-sized number. I don't know how many cases you have pending.

Dr. Gramm. Actually, that is why when we have found people who are violating the law—we are, for example, for those that are pleading——

Mr. Whitten. How many employees do you have now?

Dr. Gramm. We have 529 for this year. We have taken action to get traders off the floor of the exchanges. For example, those that have pled guilty to the charges that were brought as a result of the FBI undercover investigation will be prosecuted administratively too. Just this past week, two traders who were caught in the FBI sting were sanctioned by the Commission. They are forever banned from being on the floor of the exchange. They may not trade even for their own account—through somebody else or through a screen or anything else—for three years; and they will never be able to handle customer accounts again. That is how you deal with people who violate the law.

Mr. Whitten. Years ago the British cotton markets practically disappeared as well as New Orleans all because the U.S. had high support prices. I'm talking about the commodity exchange. Because the government was holding huge stocks the processors didn't have to carry much of an inventory. As a result, I can see why they would like to have a lower price support system because they had no ups and downs for those that deal with the exchanges. But it looks to me like the farmer just comes out second best. You can't give us any idea what the outlook is for further authorization. Have you got any indication how long——

JURISDICTIONAL ISSUES

Dr. Gramm. Not anything new at this point in time. The jurisdictional debate has stalled it.

Mr. **Whitten**. Mr. Smith is back. He still has some questions to ask I think.

Dr. **Gramm**. But I would mention that the——

Mr. **Whitten**. What is the outlook on an agreement?

Dr. **Gramm**. About what?

Mr. **Whitten**. Agreement on renewing your authorization.

Dr. **Gramm**. On the reauthorization it is hard to predict, but I would point out that Senators Leahy and Lugar have sent a letter to the Secretary of the Treasury asking his views on addressing jurisdictional issues at some later time so that we can move on and finish reauthorization and get the authorities that this agency needs.

Mr. **Whitten**. Did you want to ask a question, Mr. Smith?

Mr. **Smith**. Yes. Thank you Mr. Chairman. The problem with that is that the jurisdiction issue has a lot to do with your budget request, doesn't it?

Dr. **Gramm**. No. The budget request is based on the jurisdiction as it exists currently.

Mr. **Smith**. I know. But if the jurisdiction is going to be changed doesn't it have some impact on your budget request?

Dr. **Gramm**. It may. It depends on what happens. But given the wide range of alternatives being considered, I think it is important that we get the authorities——

Mr. **Smith**. What if your budget request is approved and then later it is found that the jurisdiction has been substantially changed?

Dr. **Gramm**. I think in that case then at that point in time make some adjustments.

Mr. **Smith**. That is not easy to do later on. Anyway, I just pointed out that it is a problem.

Mr. **Whitten**. Thank you again. We will have to wait a while and see what happens, I suppose.

Dr. **Gramm**. Thank you very much. We will keep you posted.

Donald L. Tendick

Donald L. Tendick is Acting Executive Director of the Commodity Futures Trading Commission.

Mr. Tendick has been involved with futures industry regulation since 1964. A native of rural central Illinois, he received his Bachelor of Science degree in agricultural industries in 1964 from the University of Illinois, and earned his Masters of Business Administration degree in business economics from the University of Chicago in 1972.

He joined the staff of the Commodity Exchange Authority, predecessor of the CFTC, following his graduation from the University of Illinois in 1964. He served for two years as an investigator for the CEA in Chicago before working in the office of the Assistant Administrator of its Washington headquarters for four years.

In 1970, Mr. Tendick returned to Chicago as Deputy Regional Director of the CEA's Central Region. In that position, he was responsible for market surveillance, market analysis, data processing and administration. He remained in that position after the CFTC succeeded the CEA until, in August of 1976, he returned to Washington as Special Assistant to the Executive Director. He has served as Deputy Executive Director from 1981.

Mr. and Mrs. Tendick and their daughter reside in Vienna, Virginia.

STATEMENT OF

DR. WENDY L. GRAMM

CHAIRMAN

COMMODITY FUTURES TRADING COMMISSION

BEFORE THE

SUBCOMMITTEE ON RURAL DEVELOPMENT,

AGRICULTURE AND RELATED AGENCIES

HOUSE COMMITTEE ON APPROPRIATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 22, 1990

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to appear here today to summarize the fiscal year 1991 Budget Request of the Commodity Futures Trading Commission. With me today are Donald L. Tendick, the Acting Executive Director of the Commission, and Madge Bolinger, the Budget Director.

The President's fiscal year 1991 Budget, which was submitted to Congress in January 1990, contained a request for $44,960,000, 595 staff years and a mainframe computer upgrade for the Commodity Futures Trading Commission. This amount is consistent with the Commission's request in September of 1989. Based upon the unprecedented events that occurred in 1989, I believe that funding at the requested level is essential if the Commission is to carry out its legislative mandate and fulfill its responsibilities in an efficient and effective manner.

UNPRECEDENTED EVENTS OF 1989

1989 was a benchmark year for the Commission. In January the Commission and the the United States Department of Justice publicly acknowledged the existence of a joint undercover investigation of futures trading at the Chicago Board of Trade and the Chicago Mercantile Exchange. So far, that investigation has resulted in the indictment of 47 traders and 1 runner from four trading pits at these exchanges.

During the third quarter the Commission, the U. S. Attorney's Office in New York and the U. S. Postal Inspection Service publicly acknowledged a joint investigation of futures trading on the New York markets which involved the service of administrative subpoenas and the execution of criminal search warrants. Also, during the summer, the Commission closely monitored the trading activity in the July soybean futures market at the Chicago Board of Trade. On July 11, 1989, the Chicago Board of Trade declared an emergency action relating to the expiration of that futures contract.

On October 13, 1989 the stock index futures markets and stock market experienced a large price decline. Since that time the Commission, the SEC and the other members of the President's Working Group on Financial Markets have been analyzing trading activities, including the impact of circuit breakers, during the period of the price decline. Recently the Commission has worked closely with other members of the Working Group to monitor the bankruptcy of Drexel Burnham Lambert Group, Inc. and its impact on Drexel's broker-dealer and futures commission merchant subsidiary.

Also, the Commission continued to work with the Congress on reauthorization legislation.

As a result of these events the Commission filed a request with OMB for an FY 1990 supplemental appropriation of $3,655,000 and 25 staff years to deal more quickly with some of the problems identified. We have forwarded this supplemental request concurrently to the House and Senate Agriculture and Appropriations Committees. We have also forwarded copies directly to members of the subcommittee in order to inform you of the status of the Commission's budgetary requirements.

THE COMMISSION'S RESPONSE

Before I briefly review some of the highlights of Commission activities during the past year, I would like to first note some of the Commission's important, and recently enhanced, oversight programs. We have expanded the Commission's trade practice surveillance program in a number of significant respects. Our rule enforcement review program, which periodically assesses exchange efforts to assure that trading is fair and efficient, covers a greater range of self-regulatory activity, including, for example, exchange audit trail systems. In addition, the Commission has continued to improve its capacity to conduct direct oversight of trading activity. In particular, the Commission is able to conduct an increased number of sophisticated trade practice investigations to identify abuses through computerized analysis of trade data. The Commission also has expanded trading floor surveillance through increased physical presence of Federal government regulators and exchange personnel in the trading pits.

Similarly, the Commission's financial oversight program also includes periodic rule enforcement reviews, financial surveillance procedures to identify circumstances that warrant intensified Commission scrutiny, direct audits of exchange member firms on a sample basis, and an early warning system to assure that incipient financial problems are detected and closely monitored.

Through our market surveillance program, the Commission monitors the daily activity of large traders in all markets to prevent price manipulation. Through our financial surveillance program, the Commission monitors the transfers of customer positions and segregated funds in connection with financially troubled FCMs or FCM mergers. During 1989, $112.1 million in customer funds, involving 7,713 customer accounts, were transferred between FCMs in bulk transfers. Finally, our ongoing enforcement efforts involve not only our own prosecution of violations of the Commodity Exchange Act, but also continuous cooperation and joint activity with a myriad of state, Federal, and foreign law enforcement agencies.

ENFORCEMENT

Commission enforcement activities focused public and Congressional attention on commodity futures and options markets and on the Commission's oversight regulation during FY 1989. The joint undercover investigation of trading in Chicago and the joint investigation of futures trading on the New York markets were two major efforts of the Commission. However, other extremely significant actions were taken.

For example, in September of 1989 the Commission filed injunctive complaints against International Trading Group, Ltd. (ITG), and Siegel Trading Company, charging them with using fraudulent sales tactics. The complaint against ITG, whose customers lost $428 million, was the largest sales solicitation enforcement proceeding in CFTC history.

On July 31, the Commission issued a 19-count administrative complaint against Philipp Brothers, Inc. (PBI), of New York, New York, and nine other respondents for violations of the registration, anti-fraud, trade practice, recordkeeping, reporting and other provisions of the Commodity Exchange Act and Commission regulations. The complaint alleged that these violations occurred in connection with the trading of cocoa futures contracts on behalf of commercial customers.

Without admitting or denying the allegations of the complaint, PBI, Phibro Corporation, Cocoa Merchants, Ltd., and Philipp Brothers Commodities Corporation consented to a Commission order requiring them, jointly and severally, to pay a civil penalty of $4 million, at that time the largest fine ever imposed by the Commission, and to cease and desist from violating the provisions of the Act and Commission regulations charged.

In fiscal year 1989 the enforcement program was responsible for placing more than $2,168,505 of customer funds and other assets under the protection of seven equity receivers appointed in injunctive actions and for imposing civil monetary penalties totaling over $7,100,400 on 47 individuals or firms.

The Commission's participation in the Chicago investigation and indictments and the New York investigation is in keeping with the aggressive role it has taken over the years in prosecuting commodity-related fraud. The CFTC's enforcement program has frequently included joint enforcement activities with the FBI, U.S. Attorney's offices, and other law enforcement agencies, both at the state and Federal level. We anticipate continuing those important efforts.

MARKET SURVEILLANCE

The market surveillance program faced major challenges during fiscal year 1989. Most significantly, substantial position concentrations by a large trader in the Chicago Board of Trade (CBT) soybean futures intensified surveillance actions by the Commission and, ultimately, the declaration of a market emergency by CBT on July 11, 1989.

In the aftermath of the drought of 1988, national soybean supplies were at very low levels as the end of the 1988/89 marketing year approached. Consequently, the surveillance staff carefully reviewed the ownership of soybeans in deliverable positions during this period to determine whether the lack of deliverable supplies could render the soybean futures market susceptible to price manipulation or congestion. The Commission's surveillance staff closely monitored the market and maintained extensive contact with the CBT surveillance staff.

The 1989 May and July soybean futures markets faced the greatest threats of a disorderly liquidation. The CFTC and CBT surveillance staffs conducted intensive, coordinated surveillance of both liquidations. Through the use of formal warnings to, and close daily monitoring of, the activities of the largest traders in the May future, a satisfactory contract liquidation was achieved. Surveillance attention was then focused immediately on the July contract, which potentially faced a greater threat than the May contract due to the accumulation of deliverable soybean supplies in the hands of Ferruzzi & Co.

As an additional regulatory tool to deal with threatened congestion in old crop grain and soy-complex futures, the CBT, through an emergency action in late May 1989, instituted exchange speculative position limits parallel to Federal limits in all of its agricultural futures. Both the CBT and CFTC met with Ferruzzi, the largest long trader in soybean futures, several times and had numerous telephone contacts to assess that trader's position and intentions and to advise the trader that an orderly liquidation of its long July futures position was expected. Despite these intensive informal efforts, which included a formal written request from the CBT's Business Conduct Committee specifying an expected daily rate of liquidation, Ferruzzi substantially maintained its position. By July 11, that position accounted for nearly 60 percent of the open interest and was four times larger than the deliverable soybean stocks not already owned by Ferruzzi.

By July 11, the price of the July soybean future already had reached unusually high premiums relative to the August future. While it appeared that Ferruzzi could acquire any soybeans they needed more economically in the cash market than by demanding futures delivery, they continued to bid less than the delivery value in the cash soybean market. After carefully considering this situation, the Commission determined to constrain the hedge exemption of Ferruzzi by not considering as bona fide hedges certain long positions in the July or August 1989 soybean futures during the last three trading days in those contracts. Ferruzzi was formally notified of this decision on the morning of July 11, 1989, as was the CBT.

After the close of trading on that day, the Board of Directors of the CBT, acting on a recommendation from the exchange's Business Conduct Committee, determined that additional exchange action was needed to assure an orderly liquidation of the July future. It declared a market emergency and ordered a scheduled liquidation of all of the largest positions in the July soybean futures over the remaining seven trading days. This exchange action was taken according to exchange rules. The rules permit the exchange to institute timely remedies whenever it believes an orderly liquidation of a contract is threatened. The Commission thoroughly reviewed the events surrounding this emergency action and presented its findings to the House and Senate Agriculture Committees in September 1989.

Surveillance staff also has been examining closely the October 1989 stock market decline. The Commission continues to work closely with the SEC and other members of the Working Group to ensure the integrity of the country's financial markets.

DIRECT REGULATION

During the year, the Commission enhanced its oversight activities and increased direct regulation of exchange activities and programs. For example, the Commission concluded its review of the audit trail systems that exchanges implemented to comply with the FY 1986 Commission regulation requiring execution times of all trades to be determined to the minute, instead of the thirty-minute period which was previously the standard. While each exchange met the initial implementation requirements established by the audit trail rule, the Commission found that each exchange still needed to improve the accuracy and verifiability of its system and to improve its use of trade timing information to better detect potential trade practice abuses.

The Commission recently adopted rules dealing with trade practice procedures for collection and preparation of trading records, and barring individuals with disciplinary histories from serving on exchange disciplinary committees, governing boards and arbitration panels. Staff also completed a study of trading practices of broker associations and the Commission instructed the staff to propose rules to define broker associations and require registration of broker association members. The Commission will consider proposed regulations to that effect in late March. The Commission also will be proposing regulations regarding oral orders and opening and closing trading period procedures. The Commission staff also completed a study of dual trading. A dual trader is one who trades for both a customer's account and his or her own account within the same trading session. The study found that dual traders do not provide more liquidity or better executions than non-dual traders. Based upon these findings, in January of 1990, the Commission proposed a rule which would restrict dual trading. The Commission staff will continue analysis of data upon implementation of any rulemaking to ensure that the rule does not impose unexpected and unnecessary costs.

INTERNATIONAL ACTIVITIES

During the fiscal year, the Commission has moved forward in three specific areas important in the international arena.

Foreign Futures and Options: For 1988 and 1989, the Commission approved applications from futures and options exchanges in Singapore, Australia, Canada and the United Kingdom to offer and sell various options contracts in the United States. These actions represent the first time the Commission has permitted the offer and sale of foreign option contracts to U.S. public customers since the options ban was imposed in 1978. The Commission also has granted an exemption to certain eligible firms located in those jurisdictions from the requirements to register with the Commission based on the Commission's determination that such firms are subject to comparable regulatory safeguards. Specifically, under its comparability program, the Commission, on a case-by-case basis, will defer to certain foreign regulatory requirements as substituted compliance with comparable Commission requirements.

Globex: In February 1989, the Commission approved the Chicago Mercantile Exchange's proposed Globex screen trading system. Globex is the first domestic futures trading system to apply innovations in communications and computer technology to an automated international system for screen trading.

The system should provide a comprehensive audit trail indicating all order entries, modifications and executions to the nearest second. The added precision of such an audit trail should also enhance the ability of the exchanges and regulators to maintain the integrity of rapidly growing international markets.

Information Sharing Arrangements: Efforts continued to increase cooperation and information sharing between the Commission and its counterparts in other counties. In September of 1988, the Commission announced that it had entered into a financial information-sharing memorandum of understanding (FISMOU) with the Securities and Investments Board of the United

Kingdom, as well as certain futures industry self-regulatory organizations in the U. S. and the U. K.

The basic purpose of the FISMOU is to provide a framework for sharing information between the CFTC and the relevant U. K. regulator regarding the financial condition of U. S. futures brokerage firms with branch offices in the United Kingdom.

The memorandum is the first information-sharing arrangement directed specifically to routine sharing of financial regulatory information in deference to another jurisdiction's financial requirements. It is also an important step in the direction of developing improved information sharing and regulatory coordination across jurisdictional boundaries in times of crisis.

In the context of its regulatory program to protect U. S. customers trading on markets outside the U. S., the Commission has cooperative information sharing arrangements with federal and certain state governments of Australia, the government of Singapore, federal and certain provincial governments of Canada and with relevant regulatory authorities in the United Kingdom.

REAUTHORIZATION

The Commission is continuing to work with the Congress on reauthorization legislation. The Subcommittee on Conservation, Credit and Rural Development of the House of Representatives developed a CFTC reauthorization bill, the Commodity Futures Improvements Act of 1989," which was approved by the House on September 13, 1989.

The Senate Agriculture Committee on November 2 approved a CFTC reauthorization bill that boosts CFTC's financial resources and strengthens CFTC oversight of self-regulation to help assure market integrity. The bill is currently waiting to be considered on the Senate floor. Both the Senate and House reauthorization bills are bipartisan efforts crafted by the respective Committees on Agriculture which address, among other things, concerns raised by the joint Federal undercover probe on the Chicago Mercantile Exchange and the Chicago Board of Trade.

REVENUES

Over the past few years there has been a call to create more revenues to fund the Commission's direct regulatory and oversight mandates. The President's FY 1991 budget includes a new transaction fee proposal which would generate an estimated $41.3 million, a major portion of the Commission's annual budget. The reauthorization bill currently before the Senate Committee also includes language supported by the Commission to raise service fees. Furthermore, the Commission recently proposed a rule change which, if approved, would provide for the total recovery of the costs now incurred by the Commission in performing rule enforcement and financial reviews of the self-regulatory organizations. This fee alone would boost the total of service fees collected by the agency by over 40 percent. The Commission's anticipated service fees for FY 1991 are approximately $1.4 million.

The Commission has also seen an increase in the fines assessed and collected as a result of administrative actions brought by our enforcement program. We believe that as we increase our efforts in this program these assessments and collections may continue to increase.

CONCLUSION

During the past year the Commission has been active in addressing a variety of issues with wide-ranging implications for the commodity futures and option markets. The events of the last year underscore the Commission's need to increase its resources more rapidly in the trade practice, surveillance and enforcement areas. The Commission is requesting an upgraded computer system, 595 staff years and $44,960,000 to oversee and regulate the U.S. commodity futures industry and enforce the law and Commission regulations.

I will be happy to answer questions from the Subcommittee.

COMMODITY FUTURES TRADING COMMISSION

1975

1991 BUDGET
EXPLANATORY NOTES

Prepared for the
Committee on Appropriations

January 1990

1975

COMMODITY FUTURES TRADING COMMISSION
2033 K Street, N.W., Washington, D.C. 20581
(202) 254-6970

Wendy L. Gramm
Chairman

January 23, 1990

The Honorable Robert C. Byrd
Chairman
Committee on Appropriations
United States Senate
Room S128
Washington, D. C. 20510

The Honorable Jamie L. Whitten
Chairman
Committee on Appropriations
United States House of Representatives
H-218 Capitol Building
Washington, D. C. 20515-6015

Dear Mr. Chairman:

With this letter, I am pleased to transmit to you the Commodity Futures Trading Commission's FY 1991 Budget Explanatory Notes. The Explanatory Notes reflect the funding level of $44,960,000 which is displayed in the President's budget. At this level the Commission will be able to fund 595 staff-years, an increase of 66 over its FY 1990 level of 529.

With this level of resources, the Commission believes it can meet its growing responsibilities under the Commodity Exchange Act. In particular, the increase will allow the Commission to devote additional resources to market surveillance, floor surveillance, market oversight and review, and enforcement.

Copies of this submission are also being transmitted to the House Committee on Agriculture and the Senate Committee on Agriculture, Nutrition and Forestry. If I can provide you with any further information on this matter, please do not hesitate to call.

Sincerely,

Wendy L. Gramm
WENDY L. GRAMM
Chairman

Attachment

cc: The Honorable Patrick J. Leahy
Chairman
Committee on Agriculture, Nutrition and Forestry
United States Senate
328A SROB
Washington, D. C. 20510-6000

The Honorable E de la Garza
Chairman
Committee on Agriculture
United States House of Representatives
1301 Longworth House Office Building
Washington, D. C. 20515-6001

COMMODITY FUTURES TRADING COMMISSION
BUDGET EXPLANATORY NOTES
FISCAL YEAR 1991

MISSION STATEMENT

The Commodity Futures Trading Commission (CFTC) administers the Commodity Exchange Act, as amended, 7 U.S.C. Section 1, *et seq*. The mission of the agency is to regulate and oversee the commodity futures industry in order to foster an openly competitive market environment that serves the economic functions of risk shifting and price discovery, and to protect the public and the markets from price manipulation and fraud.

The major program activities of the Commission are (1) Agency Direction; (2) Enforcement; (3) Market Surveillance, Analysis and Research; (4) Contract Markets, Regulatory Development and Oversight Audits; (5) Administrative Management and Support; (6) Proceedings; and, (7) Legal Counsel. These program activities are carried out in Washington, D. C. and in regional offices located in Chicago, New York, Kansas City and Los Angeles. A branch office operates in Minneapolis.

SUMMARY

The Commodity Futures Trading Commission was established in 1975 as an independent agency to regulate the U. S. commodity futures and option industry. The Commission has spent much of its first 14 years developing regulations and policies which emphasize surveillance of the markets; prevention of manipulation, abusive trade practice and fraud in the marketplace; oversight of self-regulatory organizations; and enforcement of the Commodity Exchange Act and Commission rules.

Fiscal year 1989 has been an eventful year for the Commission. During the second quarter of fiscal year 1989 the Commission proposed rules to clarify regulatory jurisdiction over hybrid instruments. In February the Commission approved rules for trading on Globex, the first electronic trading system approved by the Commission. In January the United States Department of Justice and the Commission publicly acknowledged the existence of an undercover investigation of futures trading at the Chicago Board of Trade and the Chicago Mercantile Exchange which in the fourth quarter resulted in the indictment of 46 traders in four trading pits at these exchanges. During the third quarter the Commission, the U. S. Attorney's Office in New York and the U. S. Postal Inspection Service issued subpoenas and served search warrants in an investigation of futures trading on the New York markets. Also, during the summer, the Commission closely monitored the trading activity in the July soybean futures market at the Chicago Board of Trade. On July 11, 1989, the Chicago Board of Trade declared an emergency action involving the liquidation of that futures contract. These investigations and related actions, together with significant policy making related to the area of off-exchange financial instruments, plus increased international cooperation among futures and option regulators made FY 1989 one of the most challenging and active years in the history of the Commission.

Because of surveillance needs made clear during the investigations in Chicago and New York, the Commission, with the support of Congress, has requested an increase in the Commission's staff and budget to provide for additional floor surveillance and related activities at the 14 designated futures exchanges. During the year, the Commission has evaluated enhanced oversight and self-regulatory procedures and participated in Congressional hearings focused on the regulation of futures and option markets.

Major projects related to enhanced oversight and self-regulatory procedures continue. The Commission is concluding its two-year review of the audit trail systems that exchanges implemented to comply with the FY 1986 Commission regulation requiring execution times of all trades to be determined to the minute, instead of the thirty-minute period which was previously the standard. While each exchange met the initial implementation requirements established by the audit trail rule, the Commission found that each exchange still needs to improve the accuracy and verifiability of its system and to improve its use of trade timing information to better detect potential trade practice abuses.

The Commission also completed a study of dual trading. A dual trader is one who trades for both a customer's account and his or her own account. The study found that dual traders do not provide more liquidity or better executions than non-dual traders. Based upon these findings, in January of 1990 the Commission proposed rules which would restrict dual trading. Additional work will be undertaken during the implementation phase of the study to ensure that the rule does not impose unexpected and unnecessary costs.

In January 1989, the Commission issued a statutory interpretation that clarified that certain hybrid instruments are excluded from the Commission's jurisdiction. In the fourth quarter, the Commission approved a regulatory exemption for other hybrids with option components that meet certain criteria. Also, at that time the Commission issued a policy statement which clarifies its view of the regulatory status of "swap transactions."

In FY 1989, in the international arena, the Commission approved applications from foreign futures and option exchanges to offer and sell various option contracts in the United States and exempted certain brokers selling foreign futures and option products from the application of certain of the Commission's rules if rules applicable in their home jurisdiction are comparable to U. S. regulations. The Commission also approved the Chicago Mercantile Exchange's proposed Globex trading system, the first electronic trade execution system at a U.S. futures exchange. With the implementation of Globex, a futures exchange will apply innovations in communication and computer technology to an automated system for screen trading of futures contracts.

On July 11, 1989, the Chicago Board of Trade declared a market emergency and ordered a scheduled liquidation of the largest positions in the July 1989 soybean futures. After the emergency, the Commission performed a thorough review of the action taken by the Exchange, declared that it was warranted, and responded to Congressional inquiries regarding it.

In addition to these major events, the Commission has continued to strengthen its surveillance of the exchanges, enhance its investigatory activities and increase its monitoring of compliance activities of the exchanges and the National Futures Association.

In order to keep up with the rapid evolution of the futures and option markets and to fulfill our statutory mandate, the Commission is requesting $44,960,000 and a staffing level of 595 for FY 1991. This is an increase of 66 staff-years over the funded FY 1990 level of 529. These 66 staff-years, 12 of which will be devoted to direct floor surveillance and related investigations, will be targeted to specific areas where the Commission must devote additional resources. A description of each of these areas follows:

Enforcement -- Twenty-three new staff-years are requested to allow the Commission to increase monitoring floor activity, including the Chicago and New York regional offices, enhance cooperation with the states, increase investigation of boiler rooms and investigating and prosecuting alleged fraud by introducing brokers. Five of these staff-years are to be devoted to floor surveillance and related investigations and litigation. These areas have required additional resources over the past few years and will continue to do so.

Market Surveillance, Analysis and Research -- Eleven new staff-years are requested for this program. Nine of these will be devoted to overall market surveillance to keep pace with the expanding contracts and markets. Two staff-years are requested to provide for additional research staff to respond to the increased requirements to analyze issues such as: the impact of dual trading on liquidity and the quality of execution, the impact of changes in regulations, policies, and procedures (e.g., the Commission's proposals resulting from the Dual Trading Study); the impact of additional delivery points in agricultural commodities; the impact of trading in the international arena; the questions of appropriate market structure and market performance which are arising from the increase in the formal and informal relationships among markets around the globe; and the advent of electronic trading. In addition to supporting the Commission's enforcement and regulatory initiatives, the research unit provides essential support to the Presidential Working Group on Financial Markets, established after the October 1987 stock market break.

Contract Markets, Regulatory Development and Oversight Audits -- Twenty-four additional staff-years are requested to enhance the Commission's oversight and audit functions. Seventeen of the staff-years will be used to keep pace with the increasing responsibilities of the Contract Markets function and to increase the number of trade practice investigations and trade practice referrals with seven of these years dedicated to floor surveillance and related trade practice activities. Two additional staff-years will be used in the Regulatory Development area to assess the need for new regulations, policies and procedures to address the alleged misconduct in the ongoing investigations and to provide additional legal support to market oversight programs and investigative authority and reports to Congress.

Two additional staff-years will enable the Sales Practice and Managed Funds area to oversee the marketing of foreign products in the United States as well as the increase in futures and option products marketed by commodity pool operators. Three additional staff-years will be for the Financial Audit and Review function to address the financial implications of growing internationalization, the integration of the futures and option markets and resultant cross-margining programs, and the need for increased financial oversight of firms and markets.

Administrative Management and Support -- Six additional staff-years are requested in this program. Three of these staff-years will be used in the Information Resources Management area for systems development; to assist in the review and audit the computer systems of the self-regulatory organizations; to review screen based trading systems for which the Commission receives proposals; to monitor the development and implementation of major industry computer system initiatives such as Globex, Entry Order System (EOS) on the Chicago Board of Trade and other automation technologies used by the exchanges; and to address the security requirements of industry and Commission systems. Two addtional staff years will be used to meet the impact of the dramatic growth of end user computing in the Commission. The other new staff-year is requested for the Office of Personnel to provide adequate support for the 66 staff-year increase in FY 1991. The Commission is also requesting additional funds in FY 1991 to acquire a new mainframe computer to allow the Commission to meet increasing requirements in monitoring the daily activities of expanding futures and option markets in accordance with the objectives of the recent five-year plan for ADP and data communications.

Legal Counsel -- Two additional staff-years are requested for the Office of General Counsel. One of these staff-years will be used in the Opinions Section to assist the Commission in ensuring timely disposition of its adjudicatory function. The other additional staff-year will provide support to handle the increased workload generated by the expected increase in the level of Commission enforcement activity.

Therefore, the Commission is submitting a budget request of $44,960,000 for fiscal year 1991 which will enable it to continue to carry out its legislative mandate and fulfill its responsibilities in an efficient and effective manner.

BIOGRAPHICAL INFORMATION ON COMMISSIONERS

Chairman Wendy Lee Gramm

Dr. Wendy Lee Gramm, from College Station, Texas, was sworn in as the Commission's fifth Chairman on February 22, 1988, in a ceremony in the White House. She was reaffirmed by President Bush on January 23, 1989.

Before joining the Commission, Dr. Gramm was Administrator for Information and Regulatory Affairs at the White House Office of Management and Budget (OMB), a position she assumed in late 1985. Prior to her service with OMB, Dr. Gramm served as assistant director and then director of the Federal Trade Commission's Bureau of Economics.

She received a B.A. degree from Wellesley College in 1966, and a Ph.D. degree from Northwestern University in 1971, both in economics. She joined the faculty of Texas A&M University in 1970, where she taught for almost nine years. After leaving Texas A&M in 1978, Dr. Gramm joined the research staff of the Institute for Defense Analyses, a defense research institute.

Commissioner Kalo A. Hineman

Kalo A. Hineman has been a commissioner since January 1982. He was nominated for a second term as CFTC commissioner by President Reagan and was confirmed by the Senate on July 24, 1986. He was sworn in on August 4, 1986. Commissioner Hineman served as acting chairman of the Commission from July 27, 1987 through February 19, 1988.

A wheat farmer and cattleman from Dighton, Kansas, Hineman received his D.V.M. degree from Kansas State University in 1943. He then served as a captain in the Army Veterinary Corps and with the Office of Strategic Services (OSS). He was a member of the Board of Directors of the First National Bank of Dighton from 1955 until December 1981, and was a member of the Kansas House of Representatives from 1975 until he joined the Commission.

Commissioner Hineman is a member of the Kansas Livestock Association (president, 1972), the National Cattlemen's Association (member, board of directors, 1971-72), the American Farm Bureau Federation and the National Association of Wheat Growers.

Commissioner Fowler C. West

In 1982, President Reagan nominated Fowler C. West, staff director of the House Committee on Agriculture, to serve as CFTC commissioner. West was sworn in on October 6, 1982. In 1988, President Reagan reappointed West to the Commission to serve a second term. He was sworn in on August 2, 1988.

At the time of his first appointment, West, a native of Bosqueville, Texas, had worked on Capitol Hill for nearly 18 years both as staff director of the House Committee on Agriculture and as administrative assistant to the late Congressman Bob Poage of Texas.

Commissioner West is chairman of the Advisory Committee on CFTC-State Cooperation and a member of the Consumer Affairs Council of the U.S. Office of Consumer Affairs, as well as the Consumer Education Advisory Council of the National Futures Association.

Commissioner West earned a B.A. degree from Baylor University in 1963, a Master's degree from George Washington University in 1980, and a Juris Doctor degree from Georgetown University Law Center in 1988. West is a member of the Virginia Bar.

Commissioner West is married to the former Anne Paine of Valdosta, Georgia. They have three sons, Fowler, Jr. 11, Mitchell Paine 8, and William Robert Poage, 5.

Commissioner Robert R. Davis

Dr. Robert R. Davis was nominated by President Reagan and confirmed by the Senate to serve as a Commissioner of the Commodity Futures Trading Commission on September 28, 1984.

Prior to joining the Commission, Dr. Davis developed broad-based financial markets expertise while serving in a variety of capacities in both the public and private sectors. He has authored numerous articles in economics, finance and public policy and serves as chairman of the CFTC's Financial Products Advisory Committee.

Dr. Davis attended Virginia Polytechnic Institute, receiving B.A., M.A., and Ph.D. degrees in economics. He served on the economics facility at Vanderbilt University in 1975 and 1976, and subsequently joined the Federal Deposit Insurance Corporation as financial economist.

Commissioner William P. Albrecht

Commissioner Albrecht was nominated by President Ronald Reagan for a recess appointment to the CFTC and was sworn in as Commissioner on December 9, 1988. He was renominated for a full term on the Commission by President Bush and was confirmed by the Senate on November 19, 1989.

Before his appointment to the Commission, Dr. Albrecht was Associate Dean for External Programs, College of Business Administration, University of Iowa, a position which began in 1987. Prior to this he served as Associate Dean for Undergraduate Programs.

Dr. Albrecht joined the faculty of the University of Iowa in 1965 as an assistant professor. In 1970, he was promoted to associate professor and in 1982 he became professor of economics. In 1986, he was a visiting professor at the University of the Andes, Merida, Venezuela.

Dr. Albrecht is the author of numerous scholarly articles, published in professional journals and several books, including Economics, Macroeconomic Principles and Microeconomic Principles. His professional research has included economic regulation and welfare programs.

Dr. Albrecht holds a Ph.D. in economics from Yale University, two Masters of Arts degress, from the University of South Carolina and Yale University, respectively, and a Bachelor of Arts degree in philosophy from Princeton University. Upon receiving his undergraduate degree, he served five years as a commissioned officer in the U. S. Navy reaching the ranking of lieutenant.

HISTORY OF THE FISCAL YEAR 1991 BUDGET REQUEST

In August 1989, the Commission voted to request $44,432,000 for FY 1991 to fund a total of 615 staff-years and to support anticipated increases in operating expenses. After submitting the Budget Request concurrently to the Office of Management and Budget (OMB) and the Congress on September 1, 1989, the Commission staff participated in an informal budget hearing on September 27, 1989.

On November 20, 1989, OMB approved an FY 1991 budget of $44,324,000 and a staff-year level of 595. The President's Budget of $44,960,000 includes an increase of $636,000 above the initial OMB passback to cover one-half of the anticipated effect of the 1991 general payraise.

SUMMARY OF INCREASES AND DECREASES

(DOLLARS IN THOUSANDS)

	FISCAL YEAR 1989 ACTUAL		FISCAL YEAR 1990 ESTIMATE		FISCAL YEAR 1991 CURRENT SERVICES		PROGRAM INCREASE REQUESTED		FISCAL YEAR 1991 BUDGET REQUEST	
PROGRAM	FUNDED FTE	AMOUNT (000)	FUNDED FTE	AMOUNT (000)	FUNDED FTE	AMOUNT (000)	REQUESTED FTE	AMOUNT (000)	REQUESTED FTE	AMOUNT (000)
MARKET SURVEILLANCE, ANALYSIS & RESEARCH										
MARKET SURVEILLANCE	70	$3,646	74	$4,131	74	$4,600	+ 9	$+ 478	83	$5,078
MARKET ANALYSIS	14	860	14	1,005	14	1,073	0	+ 3	14	1,076
MARKET RESEARCH	10	635	14	783	14	841	+ 2	+ 230	16	1,071
ALLOCATED DIRECTION/SUPPORT	41	3,221	42	3,501	42	3,996	0	- 21	42	3,975
TOTAL PROGRAM	135	$8,362	144	$9,670	144	$10,510	+ 11	$+ 690	155	$11,200
ENFORCEMENT										
ENFORCEMENT	142	$8,854	143	$9,587	143	$10,364	+ 23	$+1,448	166	$11,812
ALLOCATED DIRECTION/SUPPORT	63	4,870	59	4,910	59	5,603	+ 3	+ 240	62	5,843
TOTAL PROGRAM	205	$13,724	202	$14,497	202	$15,967	+ 26	$+1,688	228	$17,655
CONTRACT MARKETS, REG DEV & OVERSIGHT AUDITS										
CONTRACT MARKETS & REGISTERED FUTURES ASSN	35	$1,843	38	$2,005	38	$2,117	+ 17	$+1,035	55	$3,152
SALES PRACTICE AND MANAGED FUNDS	13	847	10	830	10	920	+ 2	+ 81	12	1,001
FINANCIAL AUDIT AND REVIEW	40	2,724	39	2,917	39	3,070	+ 3	+ 155	42	3,225
REGULATORY DEVELOPMENT & REGISTRATION	15	968	15	977	15	1,101	+ 2	+ 185	17	1,286
ALLOCATED DIRECTION/SUPPORT	46	3,564	42	3,501	42	3,996	+ 5	+ 436	47	4,432
TOTAL PROGRAM	150	$9,946	144	$10,230	144	$11,204	+ 29	$+1,892	173	$13,096
PROCEEDINGS										
PROCEEDINGS	27	$1,749	28	$1,879	28	$1,960	0	$+ 65	28	$2,025
ALLOCATED DIRECTION/SUPPORT	12	925	11	960	11	1,096	0	- 112	11	984
TOTAL PROGRAM	39	$2,674	39	$2,839	39	$3,056	0	$- 47	39	$3,009
TOTAL ALL PROGRAMS	529	$34,706	529	$37,186	529	$40,737	+ 66	$+4,223	595	$44,960
EXECUTIVE DIRECTION AND SUPPORT										
AGENCY DIRECTION	44	$3,137	40	$3,089	40	$3,223	0	$+ 25	40	$3,248
ADMINISTRATIVE MANAGEMENT AND SUPPORT	85	7,257	81	7,446	81	9,002	+ 6	+ 381	87	9,383
LEGAL COUNSEL	33	2,186	33	2,337	33	2,466	+ 2	+ 137	35	2,603
SUMMARY TOTAL	162	$12,580	154	$12,872	154	$14,691	+ 8	$+ 543	162	$15,234

OBJECT CLASSIFICATION
(THOUSANDS OF DOLLARS)

		FY 1989 Actual	FY 1990 Estimate	FY 1991 Estimate
Direct Obligations:				
Personnel Compensation:				
11.1	Full-Time Permanent	$19,595	$20,875	$24,915
11.3	Other than full-time Permanent	943	1,112	1,262
11.5	Other Personnel Compensation	681	740	799
11.8	Special Personnel Services Payments	19	15	20
11.9	Total Personnel Compensation	21,238	22,742	26,996
12.1	Personnel Benefits: Civilian	3,635	4,179	5,274
13.0	Benefits for Former Personnel	24	24	--
21.0	Travel and Transportation of Persons	662	739	905
22.0	Transportation of Things	27	17	19
23.2	Rental Payments to Others	4,133	4,703	5,249
23.3	Communications Utilities and Miscellaneous Charges	1,277	1,451	1,498
24.0	Printing and Reproduction	174	212	216
25.0	Other Services	1,488	1,885	2,178
26.0	Supplies and Materials	532	534	603
31.0	Equipment	1,516	700	2,022
42.0	Payment under Equal Access to Justice Act.	--	--	--
99.0	Subtotal, Direct Obligations	$34,706	$37,186	$44,960
99.0	Reimbursable	10	20	20
99.0	Total Obligations	$34,716	$37,206	$44,980

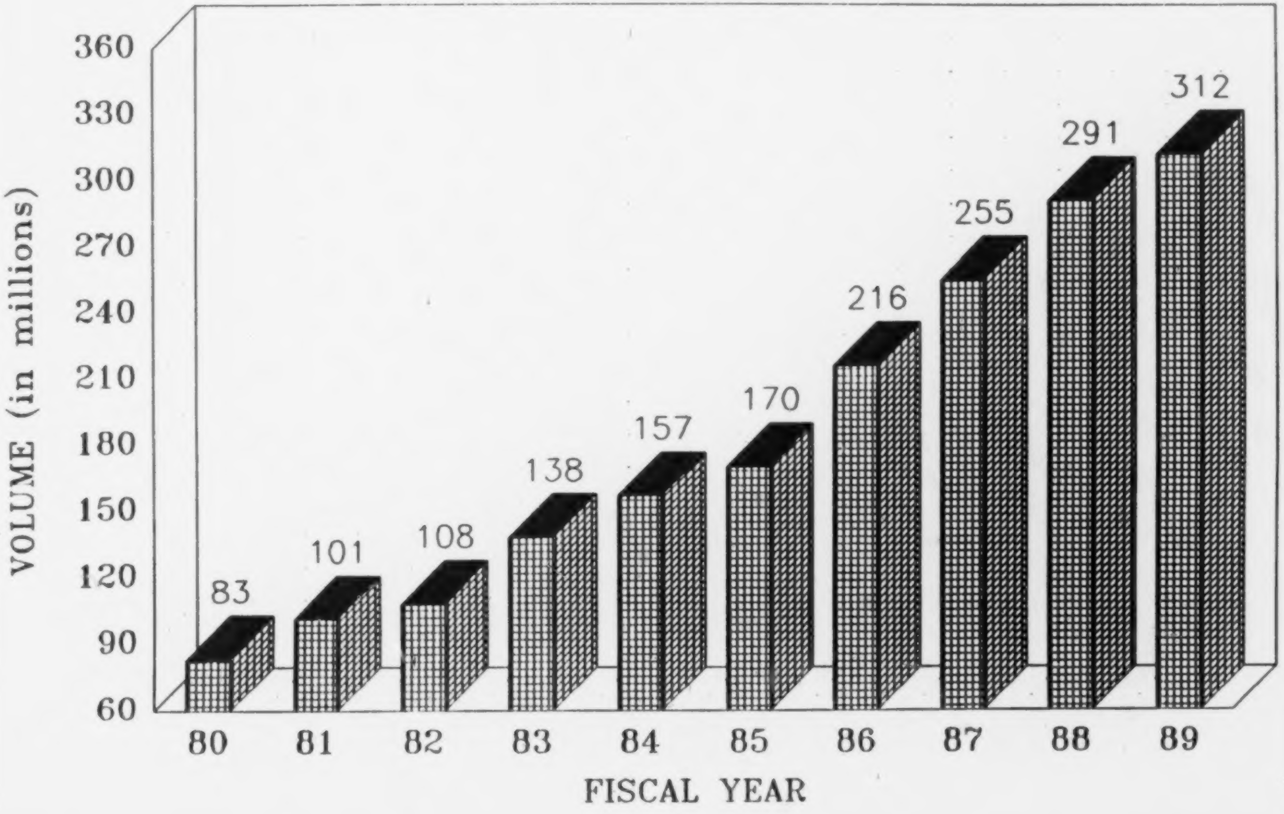
Advisory and consultant service contracts required to support the administration of the Commodity Exchange Act are estimated to be $63,000 for fiscal year 1991.

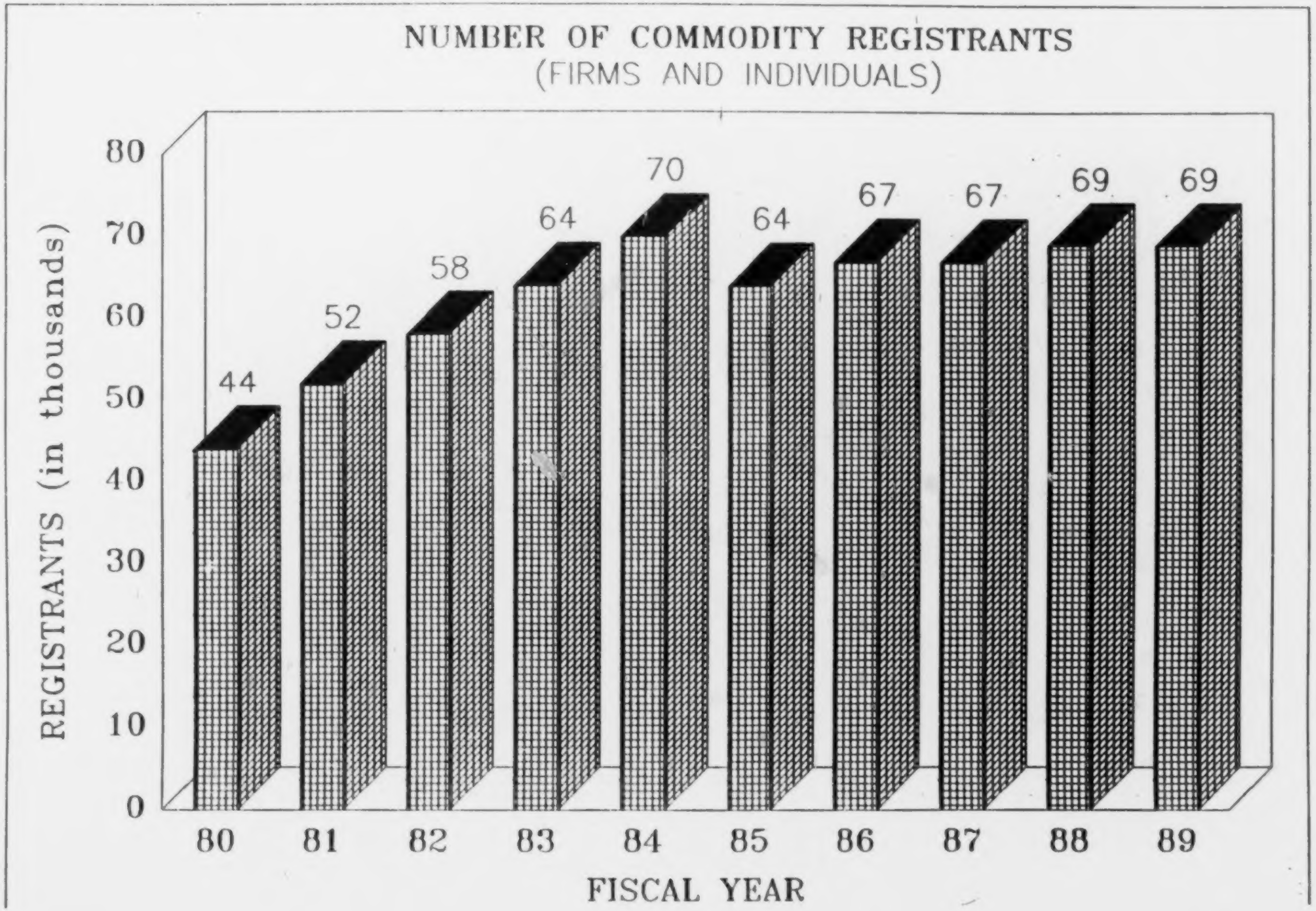
DETAILED STATEMENT OF OBLIGATIONS AND EMPLOYMENT BY GEOGRAPHIC LOCATION
(Amounts in Thousands)

LOCATION OF OBLIGATIONS:	FY 1989 Actual	FY 1990 Estimate	FY 1991 Estimate
CALIFORNIA	$ 1,482	$ 1,599	$ 1,933
DISTRICT OF COLUMBIA	23,260	24,915	30,123
ILLINOIS	5,584	5,987	7,239
MINNESOTA	122	149	180
MISSOURI	530	558	674
NEW YORK	3,728	3,978	4,811
Total Direct Obligations	$ 34,706	$ 37,186	$ 44,960

LOCATION OF EMPLOYMENT (STAFF-YRS):			
CALIFORNIA	25	25	28
DISTRICT OF COLUMBIA	324	324	365
ILLINOIS	99	99	111
MINNESOTA	2	2	2
MISSOURI	10	10	11
NEW YORK	69	69	78
Total Staff-Years	529	529	595

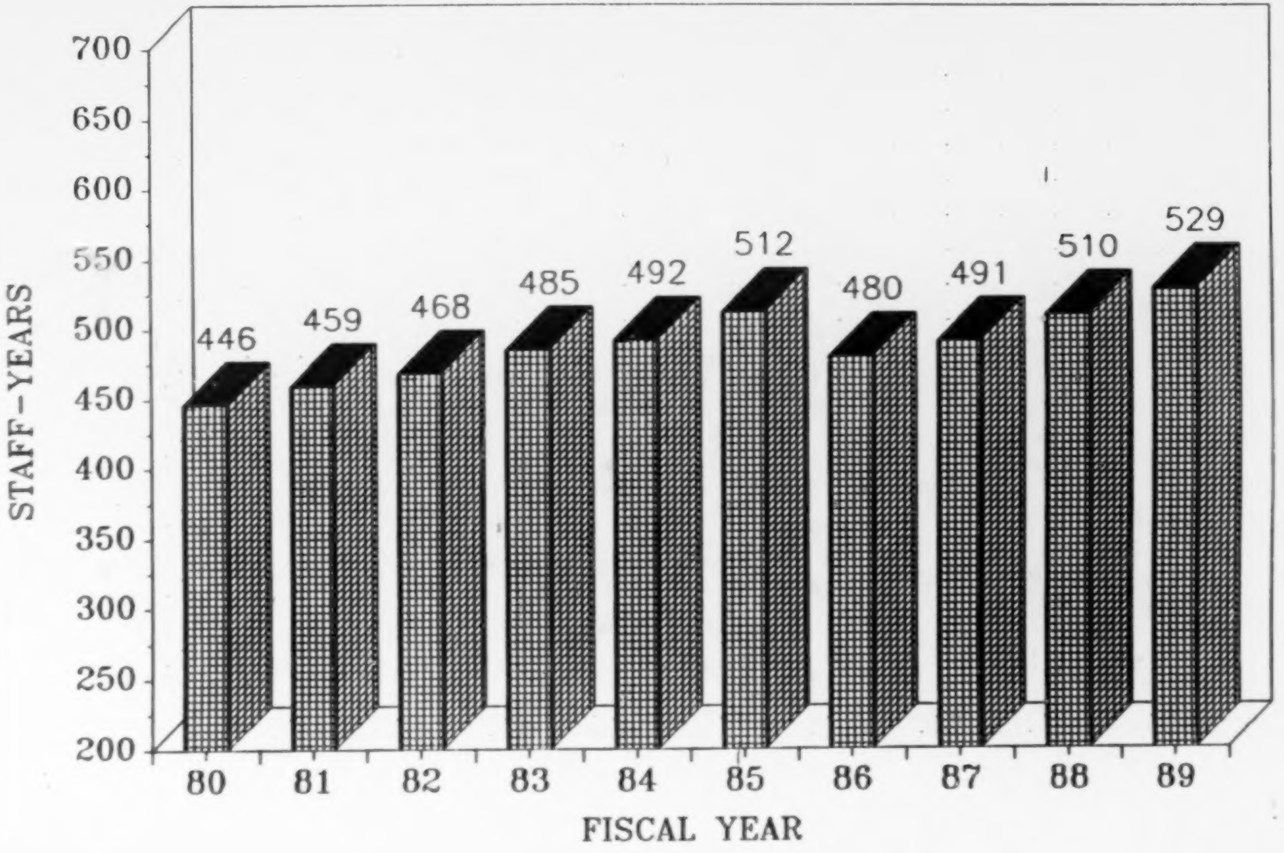
VOLUME OF TRADING IN FUTURES AND OPTIONS CONTRACTS





NUMBER OF COMMODITY REGISTRANTS
(FIRMS AND INDIVIDUALS)

NUMBER OF CFTC STAFF



MAJOR ACTIVITIES OF CFTC OFFICES AND DIVISIONS

OFFICES OF THE CHAIRMAN

- Liaison with Congress, Federal Agencies & Foreign Governments
- Public Information, Education and Publications
- Secretariat/FOIA Office
- Inspector General

EXECUTIVE DIRECTOR

- Administration & Resource Management
- Long-range Planning
- Information Resources Management
- Personnel
- Budget & Fiscal Operations
- Procurement
- Administrative Services
- Proceedings in Administrative Law and Reparations
- Library

OFFICE OF GENERAL COUNSEL

- Legal Advisor to Commission
- Appellate Litigation
- Amicus Curiae Briefs
- Bankruptcy Litigation
- Draft Commission Orders and Opinions
- Review for Legal Sufficiency
- Draft Regulations and Legislation
- Defensive Litigation
- Ethics and Financial Disclosure Advice
- Freedom of Information Act Appeals
- Legal Support to Operating Divisions
- Statutory Interpretation

ECONOMIC ANALYSIS

- Futures and Option Market Surveillance
- Speculative Limit Rule Enforcement
- Research and Special Studies
- Economic Analysis of Contract Designations
- Economic Review of Changes to Contract Terms and Conditions
- Analysis of Leverage Registration Applications

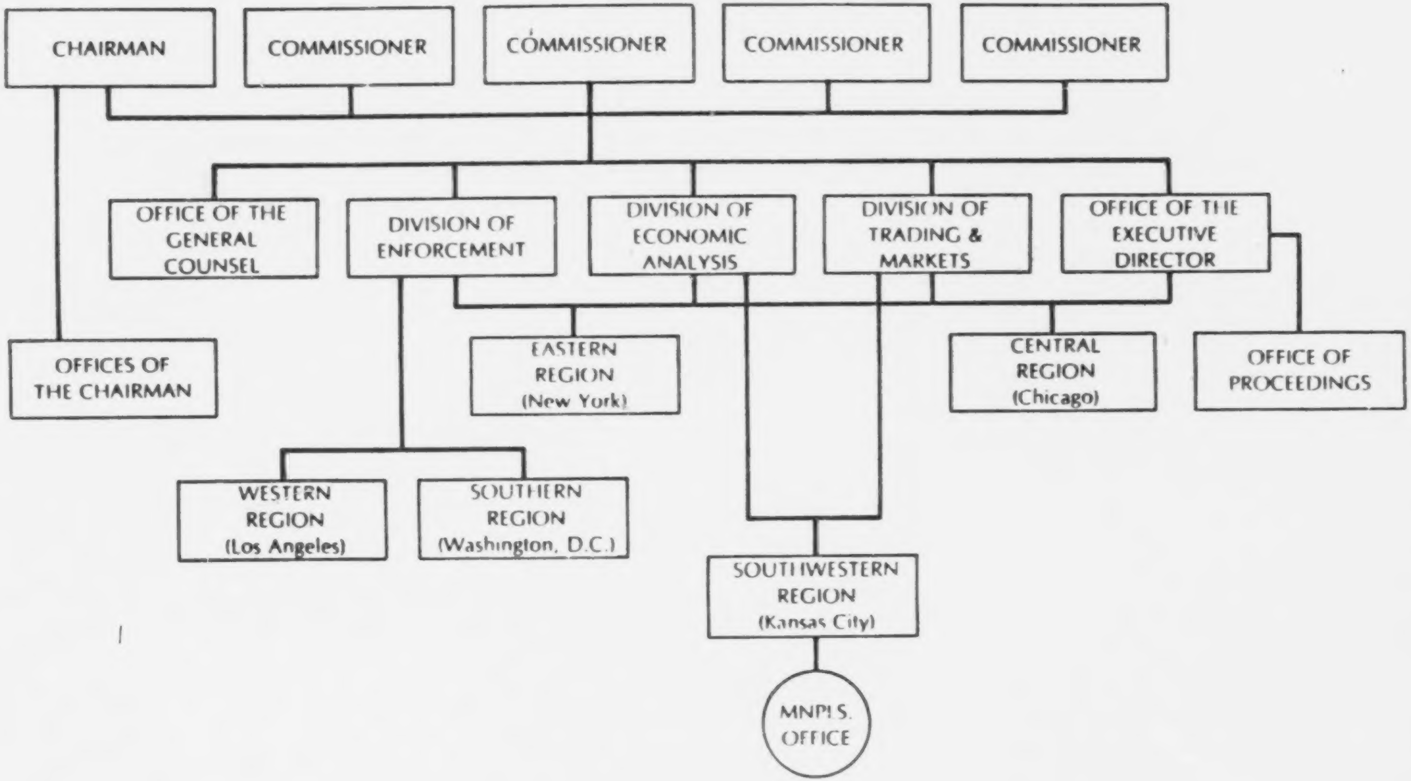
ENFORCEMENT

- Investigations
- Civil Injunctive Actions
- Administrative Actions
- Criminal Referrals
- Assistance to State and Federal Enforcement Agencies

TRADING & MARKETS

- Oversight of Exchanges and NFA
- Investigative Audits
- Rule Enforcement and Financial Reviews
- Sales Practice Reviews
- Trade Practice Investigations
- Review of Contract Market Designations and Leverage Applications
- Review of Contract Market Rules
- Draft Regulations
- Registration of LTMs and APs of LTMs
- Financial Emergencies
- Exemptions and No-action Positions

Commodity Futures Trading Commission/Organizational Chart


CHAIRMAN
COMMISSIONER
COMMISSIONER
COMMISSIONER
COMMISSIONER
OFFICE OF THE GENERAL COUNSEL
DIVISION OF ENFORCEMENT
DIVISION OF ECONOMIC ANALYSIS
DIVISION OF TRADING & MARKETS
OFFICE OF THE EXECUTIVE DIRECTOR
OFFICES OF THE CHAIRMAN
EASTERN REGION (New York)
CENTRAL REGION (Chicago)
OFFICE OF PROCEEDINGS
WESTERN REGION (Los Angeles)
SOUTHERN REGION (Washington, D.C.)
SOUTHWESTERN REGION (Kansas City)
MNPLS. OFFICE

AGENCY DIRECTION

The Commission develops and implements agency policy under the Commodity Exchange Act. It also acts to ensure the financial integrity and economic utility of commodities markets for hedging and price discovery by encouraging market competitiveness and efficiency, by active market and financial surveillance, and by protecting the public and market participants against manipulation, fraud and other abuses.

The Commission provides agency direction by reviewing each quarter's program accomplishments and by determining goals and objectives for the forthcoming quarter within the current context of economic, legal and administrative issues.

Resource Changes (FY 1991)

The Commission estimates that an increase of $159,000 is required to maintain the Agency Direction program in FY 1991. The increase requested will maintain the funded FY 1990 staffing level and provide for a share of the Commission's anticipated increase in operating expenses for FY 1991. Total request for FY 1991: $3,248,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	44	40	40
Obligations (000):			
Comp/Benefits	$2,467	$2,418	$2,551
Other (Direct)	152	168	197
Other (Pro rata)	518	503	500
Total	$3,137	$3,089	$3,248

Accomplishments (FY 1989)

Commission Activities

Commission enforcement activities focused public and Congressional attention on commodity futures and options markets and on the Commission's oversight regulation during FY 1989. In January 1989, the United States Department of Justice and the Commission publicly acknowledged the existence of an undercover investigation of trading at the Chicago Board of Trade and at the Chicago Mercantile Exchange. During the third quarter of FY 1989, Federal agents, including officials from the Commodity Futures Trading Commission, the U.S. Attorney's Office in New York, and the U.S. Postal Inspection Service, issued subpoenas and used search warrants in an investigation of futures trading on the New York markets.

Since the Chicago investigations became public in January, the U.S. Senate Committee on Agriculture, Nutrition and Forestry and the Subcommittee on Conservation, Credit, and Rural Development of the House of Representatives' Agriculture Committee have asked the Commission to review and evaluate its regulatory oversight procedures and to participate in Congressional hearings focused on the regulation of futures and option markets.

The Commission's review of oversight procedures and exchange trading practices coincided with the end of a two-year Commission study of the audit trail systems which nine exchanges implemented to meet the Commission's 1986 requirement that the minute of trade execution be determined for all trades.

The Commission concluded that while the audit trail systems generally were adequate at this initial stage of implementation, each exchange could improve the accuracy and verification of its system and its use of trade timing information in its own trade practice surveillance program. The Commission specifically directed that exchanges review the verifiability of timing data and the accuracy of source records, such as order tickets and trading cards. Furthermore, the Commission asked exchanges to ensure that procedures are in place to permit prompt detection and adequate disciplinary sanctioning of exchange members who do not comply with recordkeeping and reporting requirements. The Commission will establish standards and timetables to ensure that the necessary improvements in the audit trails systems are implemented.

Dual Trading

During FY 1989, the Commission also requested each exchange to provide data to assist the Commission in an assessment of dual trading. In the past, the Commission has expressed its concern that exchange audit trail systems be sufficient to address the potential for dual trading abuses. In March 1989, the Commission reiterated its concern that audit trail systems be effective for detecting dual trading abuses, and also asked whether limitations on dual trading could address certain types of trading abuses and whether restrictions on dual trading might unduly limit liquidity for particular markets.

A study conducted by the Commission's Division of Economic Analysis, released in early FY 1990, examined the practice of single traders executing personal trades and trades for customers within the same day, a practice permitted on most U.S. and international futures exchanges. The study examined an extensive record of trading activity--more than 4.2 million futures transactions and 400,000 option transactions--in U.S. futures and option markets to determine the extent of dual trading and some of its characteristics. The study also sought to determine if there is statistical support for assertions that dual trading is necessary for adequate market liquidity and that it leads to superior trade execution.

In summary, the study found:

- Dual traders tend to specialize in trading either for themselves or for customers.

- The incidence of dual trading does not appear to be higher for low volume markets or more distant trading months.

- Dual traders do not, on average, provide better execution for customers than do exclusive brokers.

- Dual traders' performance in providing market liquidity is not superior to that of exclusive traders.

Following release of the study, the Commission in January 1990 proposed a rule which would prohibit a floor broker from trading or placing a commodity futures or option order for his own account, an account that he controls or an account in which he has an interest while holding or executing a customer order in the same commodity during the same trading session.

The Commission's proposal provides that the rule, regulation 155.5, will apply on a provisional basis, to one or two of the most actively-traded commodities on each of the seven largest futures exchanges, to collect and analyze data on the effect of the restriction, and to expand and refine its examination of historical data during a 12-month implementation period.

This proposed dual trading prohibition is subject to certain exceptions, deemed permissible by the Commission and specified in each exchange's rules.

Broker Associations

In response to questions raised by last year's undercover investigation into floor trading practices at several futures exchanges, the Commission's Division of Trading and Markets reviewed the organization and trading procedures of certain broker groups, sometimes known as "broker associations."

The report included recommendations for proposed new rules which would define "broker associations" and require exchanges to register members of these associations. The Commission has directed the Division of Trading and Markets to draft rules to require the identification of broker association members and to monitor their trading activity.

Off-Exchange/Hybrids

In December 1987, the Commission invited public comment on an advance notice of proposed rulemaking for certain off-exchange financial instruments with some futures-like or option components. The notice generated a good deal of controversy and comments. The instruments involved included debt and depository instruments, like a certificate of deposit whose return is linked to fluctuations in the price of gold, or a debt security tied to exchange-rate fluctuations.

The advent of these "hybrid" instruments fostered questions about regulatory jurisdiction which the Commission addressed through a statutory interpretation issued in January 1989 clarifying that certain hybrid instruments are excluded from the Commission's jurisdiction. At the same time, the Commission proposed a regulatory exemption for other hybrid instruments with option components that meet certain criteria. The final rule regarding that exemption was approved by the Commission in the fourth quarter.

Also, in the fourth quarter, the Commission issued a policy statement which clarifies its view of the regulatory status of swap transactions. The statement recognizes a non-exclusive "safe harbor" for transactions meeting specified requirements.

The Commission will continue to respond to requests for interpretation and jurisdictional clarification and will continue to work with other regulatory agencies to avoid regulatory duplication, gaps, or uncertainty.

International

In addition, during the fiscal year, the Commission has moved forward in three specific areas important in the international arena.

Foreign Futures and Options: The Commission has approved applications from futures and options exchanges in Singapore, Sydney, and Montreal to offer and sell various options contracts in the United States and to permit certain brokers selling their futures and option products to do business in the U.S. under rules applicable in their home jurisdiction. The Commission also granted an exemption from some of the Commission's futures and options rules to certain eligible United Kingdom firms subject to comparable regulatory safeguards. These actions represent the first time the Commission has permitted the offer and sale of foreign option contracts to U.S. public customers since the 1978 ban on options.

Globex: In February 1989, the Commission approved the Chicago Mercantile Exchange's proposed Globex trading system.

Globex is the first domestic trading system to apply innovations in communications and computer technology to an automated international system for screen trading of futures and options contracts.

The system should provide a comprehensive audit trail indicating all order entries, modifications and executions to the nearest second. Such innovation should also enhance the ability of the exchanges and regulators to maintain the integrity of rapidly growing international markets.

Information Sharing Arrangements: Efforts continued this year to increase cooperation and information sharing between the Commission and its counterparts in other counties. On September 15, 1988, the Commission announced that it had entered into a financial information-sharing memorandum of understanding (FISMOU) with the Securities and Investments Board of the United Kingdom, as well as certain futures industry self-regulatory organizations in the U. S. and the U. K.

The basic purpose of the FISMOU is to provide a framework for sharing information between the CFTC and the relevant U. K. regulator regarding the financial condition of U. S. futures brokerage firms with branch offices in the United Kingdom.

The memorandum is the first information-sharing arrangement directed specifically to routine sharing of financial regulatory information in deference to another jurisdiction's financial requirements. It is also an important step in the direction of developing improved information sharing and regulatory coordination across jurisdictional boundaries in times of crises.

Efforts are continuing to increase cooperation between the Commission and its counterparts in other countries, primarily through agreements which provide a framework for sharing information.

Market Surveillance

Congested market conditions developed in several markets this year. In particular, a tight supply situation in soybeans caused the spot May and July 1989 contracts to move to unusually large premiums to deferred months. Surveillance staff maintained close contact with exchange officials and with large traders and carefully examined the actual hedging needs of several traders during these congested liquidations. As an additional regulatory tool to deal with threatened congestion in old crop grain and soy-complex futures, the exchange, through an emergency action in late May 1989, instituted exchange speculative position limits parallel to Federal limits in all of its agricultural futures.

In a subsequent emergency action, on July 11, 1989, the exchange ordered a scheduled liquidation of the largest positions in the July 1989 soybean futures. This exchange action was taken pursuant to rules of the exchange and is consistent with the exchange's responsibilities. The rules permit the exchange to institute timely remedies whenever they believe an orderly liquidation of a contract is threatened. The Commission also modified the hedge exemption of the largest long trader. After the emergency, Surveillance staff assisted in the Commission's review of the action and in responding to congressional inquiries regarding it.

Presidential Working Group

The Commission also participated in the Presidential Working Group on Financial Markets formed to address issues raised by the October 1987 Stock Market Break. In the past year, exchanges and market regulators have initiated many of the Working Group's recommendations. For example, coordinated circuit breaker mechanisms have been implemented across securities and futures markets and credit, clearing and settlement systems have been improved to facilitate more efficient cash flows.

In mid-October 1989 the stock index futures markets and the stock market experienced an abrupt, large price drop. The CFTC and the Securities and Exchange Commission, along with the other members of the Working Group, are analyzing trading activities, including the impact of circuit breakers, during the period of the price decline.

Reauthorization

The Commission is continuing to work with the Congress on reauthorization legislation. The Senate Agriculture Committee on November 2 approved a CFTC reauthorization bill that boosts CFTC's financial resources and strengthens CFTC oversight of self-regulation to help assure market integrity. The bill is currently waiting to be considered on the Senate floor.

The Subcommittee on Conservation, Credit and Rural Development of the House of Representatives developed a CFTC reauthorization bill, the Futures Trading Improvements Act, which was approved by the House on September 13, 1989. Both the Senate and House reauthorization bills are bipartisan efforts crafted by the respective Committees on Agriculture in response to concerns raised by a federal undercover probe which targeted the Chicago Mercantile Exchange and the Chicago Board of Trade.

Offices of the Chairman

The Office of Communication and Education Services, the Office of Congressional and Governmental Affairs, the Office of the Secretariat and the Office of the Inspector General work closely with the Commission to facilitate and implement agency policy

Office of Communication and Education Services

The Office of Communication and Education Services (OCES) serves as Commission liaison with the news media, producer and market user groups, and the general public to inform them about the role of futures markets, new market instruments, market regulation, and the functions of the Commission.

During FY 1989, OCES worked with more than 265 domestic and foreign news correspondents. In addition to providing them with approximately 215 news releases and advisories, the office conducted several briefings and backgrounders on technical issues, including hybrid instruments, international information-sharing agreements, the regulatory oversight function of the Commission, and cooperative enforcement actions relating to alleged trading violations on several New York and Chicago exchanges.

OCES published and distributed each week 1,000 copies of the Advisory Calendar, which reports official Commission activities, and during the year distributed approximately 63,500 brochures, newsletters, and reports concerning the Commission's regulatory programs and basic facts about futures markets. OCES' Daily Newsclips, which reflect the news in more than 40 periodicals, 14 dailies, 20 weeklies, and three wire services, were distributed to more than 400 individuals and organizations each day.

OCES provided information to consumers about the function and purpose of futures markets and the role of the Commodity Futures Trading Commission, as well as about off-exchange commodity fraud, through organizations like the National Association of Retired Persons, the President's Consumer Affairs Council, the Better Business Bureau and the National Consumers' League. In addition, the office handled 14,500 telephone calls from futures market customers seeking futures-related information.

As in past years, OCES worked closely with the Commission's Agricultural Advisory Committee, as well as with many agricultural and education-oriented groups to provide information about futures market issues and to learn about their concerns and views about market and regulatory issues. During the year, OCES also offered several internal training sessions for new CFTC employees to acquaint them with the purpose and function of futures markets and the organization and activities of the Commission. OCES also published an updated version of the Proceedings Bulletin during the third quarter of FY 1989.

Office of the Secretariat

The Office the Secretariat continues to provide essential administrative support to the Chairman, Commissioners, and other staff offices. Meeting this responsibility involves many functions, such as maintaining official agency records, scheduling Commission meetings, responding to Freedom of Information, Privacy and Sunshine Acts requests, and providing information to the public and CFTC staff.

In addition to tasks involving records maintenance, the staff handles several thousand inquiries annually from both the Commission staff and the general public concerning information contained in the official records. The staff also received and processed approximately 500 requests for nonpublic Commission records and 1,000 petitions for confidential treatment.

In addition to its routine tasks, functions, and activities, the Secretariat staff undertook several special projects in FY 1989. The conversion of the records system in the office to microfilm continued, as did the automation of various logs and indexes of the Commission's official records. The FOIA staff completed its project to compile an automated digest of FOIA appeals to assist in their processing of initial requests received by the Commission.

Office of Congressional and Governmental Affairs

FY 1989 was a reauthorization year for the Commodity Futures Trading Commission. Most activities involving the Office of Congressional and Governmental Affairs (OGCA) were related to the reauthorization process. During the second and third quarter, the Chairman, senior staff and OCGA addressed Congressional questions concerning cooperative enforcement actions relating to alleged trading violations on several New York and Chicago exchanges.

In preparation for reauthorization hearings, OCGA coordinated communications among the Commission and Members of Congress and their staffs. OCGA expects to continue to increase contact with Members of Congress and their staffs as the Commission seeks to broaden understanding of futures markets and the regulatory role of the Commission as the reauthorization process continues.

During FY 1989, OCGA conducted individual and group staff briefings on issues involving the October 1987 stock market price break, cattle futures trading and the Chicago Board of Trade soybean market emergency. Other briefings dealt with the self-regulatory system--including the role of the exchanges and that of the Commission as oversight regulator--within the context of the enforcement investigations in Chicago and New York. In addition, OCGA continued its daily contact with Member-offices, the Commission's legislative authorizing committees and appropriations committees, as well as handling constituent problems in response to Congressional inquiries.

Office of the Inspector General

The Office of the Inspector General was created on April 14, 1989 in accordance with the Inspector General Act of 1978 (P.L. 95-452), as amended by the Inspector General Act Amendments of 1988 (P.L. 100-504). An Inspector General was appointed in September, 1989. The Office consists of the Inspector General and two staff members.

The Office is charged to promote economy, efficiency, and effectiveness in the administration of CFTC programs and operations and to detect and prevent fraud and abuse in such programs and operations; conduct and supervise audits and, where necessary, investigations relating to the administration of CFTC programs and operations; assess the impact of existing and proposed legislation and regulations to determine their impact on the economy, effectiveness, and efficiency of agency programs and operations; and, keep the Chairman and Congress fully informed about any problems or deficiencies in the administration of CFTC programs and operations and provide recommendations for correction of these problems or deficiencies.

In November, 1989, the Office published its first Semiannual Report to Congress in which it provided a description of Office procedures and resources as well as its audit agenda. As reflected in this Report, insofar as possible, the Office will focus its efforts on creating an environment that will promote the agency's long-term effectiveness and efficiency and foster innovation in its programs and operations. The Office will solicit additional assistance from other Federal agencies and private persons and associations as necessary to achieve these objectives.

As part of its first agenda, the Office will review several critical administrative programs, such as the evaluation of the agency's fee determination procedures and its ADP planning process. The Office also will initiate reviews of operational programs, such as the agency's response to the development by the exchanges of automated trading systems and computer support systems, the internal training programs for CFTC staff, and the agency's review of exchange trade practice programs. The progress in all areas listed in the agenda will be reported in subsequent Semiannual Reports.

Planned Activities (FY 1990)

In FY 1990 the Commission will assign high priority to regulatory activities that are related to the alleged abuses identified in the investigations in New York and Chicago and during reauthorization. In addition, the Commission in FY 1990 will continue to focus on oversight of market activity, as well as to address intermarket regulatory issues raised by the events of October 1987 as a participant in the President's Working Group on Financial Markets. The Commission will continue to work with the futures and option exchanges to implement regulatory changes in all futures markets and to improve intermarket coordination.

During FY 1990, one priority on the Commission's agenda will involve international issues, including: monitoring rules to permit the offer and sale of foreign futures and options in the U.S.; reviewing and monitoring the development of new systems and international links to trade futures and options around the world; and establishing additional cooperative information sharing arrangements with other governments in response to the internationalization of these markets. One of the areas that will require close attention deals with computerized trading in the international markets. At present, the Chicago Mercantile Exchange has received approval of this type of system (Globex) and the Chicago Board of Trade is discussing one (Aurora). The Commission will continue to assess the computer security aspects of these systems.

During FY 1990, the Commission will continue its Advisory Committee on CFTC/State Cooperation which encourages the states to prosecute fraudulent commodity activities wherever jurisdictionally appropriate. The agency will also continue its Agricultural Advisory Committee and Financial Products Advisory Committee which advise the Commission on a broad range of agricultural and financial market issues. Also, during the year, the Commission will establish the Regulatory Coordination Advisory Committee to assist the Commission in dealing with other stock and futures markets regulators and market users worldwide. The Committee will focus on regulatory coordination and regulatory gaps, as well as regulatory duplication.

In the coming year, the Office of Congressional and Governmental Affairs staff will continue serving an expected growing level of Congressional interest in the functions, operations, and jurisdiction of the futures markets, especially financial derivative markets. The Office of Congressional and Governmental Affairs also will continue to develop and enhance the working relationship between the CFTC, appropriate Congressional committees, individual Congressional offices, other Federal agencies, and the states. The focus of these activities will be on sharing information and providing background for proposed legislative and administrative actions as the Commission goes through and completes the reauthorization process.

The Secretariat will continue providing administrative support to the Commission, as well as performing the activities of records management and processing FOIA, Privacy and Sunshine Act requests. In addition, the Secretariat will continue to convert official Commission records to microfilm, and enhance and expand its records automation program.

OCES will continue to provide educational seminars and information upon request. In addition, further work will be done in OCES to develop resource files on economic and legal subject areas to improve the level of knowledge about the Commission among relevant press. OCES will complete computerizing its historical and current press release and advisory files. Additionally, OCES will continue to provide information to the public and to provide internal training to CFTC staff.

In FY 1990 the Office of Inspector General will continue its review of Commission activities as required by the Inspector General Act of 1978, as amended in 1988.

Justification of Current Level (FY 1991)

During FY 1991, the Offices of the Chairman and Commissioners will be able to continue to perform all of their review and oversight responsibilities over a continually expanding industry at the same staffing level as FY 1990.

ENFORCEMENT

The Division of Enforcement operates the Commission's Enforcement program. The Enforcement program seeks to ensure compliance with the provisions of the Commodity Exchange Act and Commission regulations through investigation and civil and administrative prosecution of alleged violations.

Enforcement activities typically begin with investigations authorized under Sections 6(b) and 8 of the Commodity Exchange Act. Staff develop investigations based on information obtained by Commission surveillance economists and auditors, referrals from federal and state government agencies, public inquiries such as customer complaints received through the Commission's reparations program, and other sources. The prompt and diligent investigation of trade practice abuses, manipulative activities, fraudulent sales practices, and other violations of the Act provides a basis for effective civil, administrative, and criminal prosecution of violators.

Commission investigations may result in enforcement litigation either in federal district court or before the Commission and its administrative law judges. Such prosecutions restrain and deter persons who would victimize customers and other market users by means of fraudulent and deceitful practices. Prosecutions under the Act and Commission regulations also protect the legitimate hedging and pricing functions of futures markets from the economic inefficiencies created by unlawful practices. As a result, enforcement activities operate to strengthen investor confidence in the integrity and utility of commodity futures and option markets.

After initial civil or administrative prosecution, the Enforcement program provides, where possible, for follow-up in the form of contempt and other proceedings to obtain compliance with court and Commission orders. Serious criminal violations are referred to the Department of Justice for prosecution and Commission staff provide expert assistance to state and federal prosecutors to the extent that resources allow.

CFTC enforcement actions cover such diverse and complex violations as:

- cheating and defrauding of customers by commodity professionals through fraudulent solicitations, churning, misallocation of trades, and otherwise;

- wash trades, accommodation trades, prearranged trading, fictitious trading, and causing non bona fide prices to be reported;

- misappropriation of customer funds;
- price manipulation;
- sale of illegal instruments;
- violations of reporting requirements;
- misrepresentation in commodity pool offerings and other solicitations;
- violation of financial integrity regulations;
- violation of recordkeeping requirements;
- misrepresentation by commodity pool operators and commodity trading advisors of trading results or fee arrangements;
- misuse of funds and commissions; and
- violations of speculative position limits.

The staff also investigates and prosecutes cases involving persons who appear unfit to be registered under the Commodity Exchange Act.

Investigations and litigation under the Commodity Exchange Act are complex and document intensive, and often involve novel issues. Unlike other remedial statutes, the Commodity Exchange Act, in its present form, is relatively new and thus has been the subject of comparatively limited judicial interpretation. Moreover, Congress enacted significant amendments to the Act in 1982 and 1986. The existence of many unresolved legal questions under the Act creates the potential for more litigation than might be expected where, for example, an older agency has benefited from many years of judicial interpretations of its enabling legislation. Federal district judges often have little experience with futures industry activities and standards, and can require much background information during the course of a case. These factors and others often lead to complex issues in enforcement investigations and litigation, with accompanying increases in resource needs.

Resource Changes (FY 1991)

The Commission anticipates that an increase of $2,225,000 is required to maintain the Enforcement Program in FY 1991. The increase requested will include twenty-three additional staff years ($1,183,000) and will provide for a share of the Commission's anticipated increase in operating expenses for FY 1991 ($1,042,000). Total request for FY 1991: $11,812,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	142	143	166
Obligations (000):			
Comp/Benefits	$6,560	$7,110	$ 8,913
Other (Direct)	619	677	818
Other (Pro rata)	1,675	1,800	2,081
Total	$8,854	$9,587	$11,812

Accomplishments (FY 1989)

During FY 1989, the Commission opened 89 new investigations, which were added to the workload of 109 investigations pending at the beginning of the fiscal year. During the same time period 68 investigations were closed. Slightly over half of the Division's professional operational staff hours were spent on investigations, with the remainder devoted to litigation and cooperative enforcement matters. During FY 1989 the Commission filed 15 civil injunctive actions and 35 administrative proceedings. The staff added these cases to its existing workload of 119 cases pending at the beginning of the fiscal year. Fifty-six cases were completed during FY 1989.

During FY 1989, the Commission confirmed its participation with the Department of Justice in an undercover investigation of trading activity on two Chicago futures exchanges. As a result of that investigation, on August 2, 1989, the Commission, with the United States Attorney in Chicago, the Department of Justice, and the FBI, announced the indictment of 46 persons on charges stemming from illegal floor trading practices on those exchanges. The allegations in the indictments included violations of the Racketeer Influenced and Corrupt Organizations Act, mail and wire fraud, and fraud in connection with futures transactions in violation of Section 4b of the Commodity Exchange Act. At that same time, the Commission announced that it had brought eight administrative enforcement actions against certain of the indicted traders, and had simultaneously accepted offers of settlement and imposed sanctions in those cases. During FY 1989, the Commission also confirmed its investigation of certain trading activity on New York futures exchanges. Both matters are ongoing.

While continuing to litigate significant, complex matters, the Commission devoted an increased portion of its enforcement resources to new and continuing investigations. These investigations addressed virtually all types of possible violations of the Act, with concentrations of staff resources in two areas. During the fiscal year, investigations concerning possible fraud by FCMs consumed nearly 30 percent of all enforcement division professional staff resources devoted to investigations, while investigations of possible trade practice abuses consumed an additional 21 percent. The Division's concentration of resources on investigations already has begun to yield results in the form of recent cases such as those alleging fraud by an FCM, and alleging trade practice violations by a large trading concern and by twenty-two floor brokers.

Those subject areas of Commission investigations receiving the highest concentration of resources were consistent with the allocation of staff resources over the last several fiscal years. One part of this concentration of resources evidences the importance of careful scrutiny of futures commission merchants who are the custodians of customer funds. Futures commission merchants' managed account programs present one of the potential areas of abuse addressed by the Enforcement program. Detecting and proving instances of churning of customer accounts or fraudulent allocation of trades is resource intensive. Such investigations require detailed analysis of trading records and other documents.

Misrepresentation, sales practice abuse and unauthorized trading are also forms of futures commission merchant fraud detrimental to customers and the integrity of futures trading. These activities also require a high level of resource commitment. Moreover, investigations of possible futures commission merchant fraud can require extensive resources simply because futures commission merchants are often larger organizations than other types of registered firms and operate through multiple branch offices or introducing brokers who are geographically dispersed.

Similarly, investigations of possible trade practice abuses are important but time consuming. These investigations and cases often involve complex legal and factual issues. They generally require staff investigators and attorneys to obtain and review voluminous trading records and to reconstruct trade sequences, often in very active markets. The Division's efforts in this area, however, yield future benefits by acting as a deterrent because they establish the principle that serious violations of the commodities law on the exchange floors will be vigorously prosecuted.

Trade practice matters usually involve floor brokers and traders, who are not members of the NFA and, accordingly, are beyond its sanctioning authority. Similarly, exchange disciplinary proceedings can address only conduct on the particular exchange and impose penalties that relate solely to that exchange. In contrast, the Commission can reach conduct that occurs across exchanges, and can prohibit individuals and firms from trading on all exchanges. Consequently, only the

Commission can fully investigate and sanction the full range of trade practice violations, which can seriously impair the price discovery and hedging functions of the futures markets.

At the same time that investigative efforts placed demands on the Commission's enforcement resources, during FY 1989 the Commission committed a significant amount of professional staff resources to cooperative enforcement matters and to major enforcement cases. For example, during FY 1989, litigation of just four cases accounted for nearly 10 percent of total Division professional resources. Like the distribution of investigative resources, the highest concentrations of litigation resources were in the areas of fraud and trade practice. As part of its litigation, the Division has, in appropriate circumstances, continued to use the authority which was granted to the Commission in the 1986 amendments to the Act to seek ex parte appointment of a receiver. During FY 1989, the Commission obtained such ex parte appointments of receivers in nine cases. The Commission is also continuing its efforts to increase the deterrent effect of fraud prosecutions against firms by taking additional enforcement actions against individual brokers and firm officers who allegedly engaged in fraudulent practices.

During FY 1989, the Division continued its program to educate state, local, and federal civil and criminal officials about the Commodity Exchange Act and commodity related fraud. The Division's State-Federal Liaison Unit organizes and presents educational programs, with support from other staff of the Division of Enforcement and other operating divisions of the Commission. The lectures and materials provided to the participants describe the operations of legitimate commodity markets, the methods employed by commodity bucket shop operators, and approaches for investigating and prosecuting commodity related offenses. Workshops are held both independently and in conjunction with other training programs sponsored by various state and federal agencies such as state securities offices, the FBI, and the North American Securities Administrators Association.

During FY 1989, over 300 people attended such programs in 12 different locations including: Portland, Oregon; Las Vegas, Nevada; Newport Beach, California; Jackson, Mississippi; Jacksonville, Florida and the FBI Academy at Quantico, Virginia. Panelists or attendees included representatives of United States Attorney's Offices, District Attorney's offices, the Attorney General's Office, the FBI, United States Postal Inspection Service, United States Customs Service, Securities and Exchange Commission, Federal Trade Commission, National Futures Association, Internal Revenue Service, state securities and banking regulators, and state and local police.

The Commission has continued and expanded its participation in the interagency Securities and Commodities Fraud Working Group. The group was organized to facilitate and encourage effective prosecution of fraud involving securities and commodities. Participants include various United States Attorneys, the Securities and Exchange Commission, Federal Trade Commission, FBI, IRS, the National Association of Attorneys General, and various securities and futures exchanges. Senior members of the Division have been participants in the Working Group throughout the past fiscal year, and have been active in three newly-organized subgroups which are addressing specialized issues. In May, Division attorneys assisted in presenting a two day educational seminar on securities and commodities fraud which was attended by over 160 enforcement officials from state, local, federal, and foreign government agencies.

During FY 1989, the Commission requested legislative authority which would permit it to assist foreign futures authorities by conducting investigations on their behalf. The authority sought by the Commission is substantially identical to the authority given to the SEC in the recent Insider Trading and Securities Fraud Act. The Commission expects that the availability of its investigative assistance to foreign futures authorities will act as a strong inducement for these authorities to obtain similar authority to assist the Commission.

Civil Injunctive Actions: The civil injunctive actions brought and injunctive relief ordered during FY 1989 in the federal district courts included:

- An injunctive action charging an unregistered individual with misappropriation and conversion of customer funds in connection with his operation as an unregistered futures commission merchant. The federal district court immediately issued an *ex parte* order freezing all assets and protecting all books and records.

- An injunctive action alleging fraud in connection with the sale of exchange traded futures and options contracts and conversion of customer funds. The federal district court immediately issued an order freezing all assets and protecting the firm's books and records. Subsequently, the court issued a preliminary injunction.

- An injunctive action charging a futures commission merchant with capitalization and recordkeeping violations. The federal district court issued a preliminary injunction and appointed an equity receiver. Thus far, $220,000 has been brought under his protection.

- An injunctive action charging an unregistered individual with fraud and conversion of customer funds. The federal district court immediately froze all assets and appointed a temporary receiver. Subsequently, the court issued a preliminary injunction. The receiver has recovered $87,000.

- A consent order of permanent injunction by a federal district court prohibiting a foreign firm from selling illegal foreign commodity options and illegal off-exchange futures contracts in the United States. The firm also agreed to pay $800,000 into the court for the benefit of customers who purchased the illegal contracts.

- An injunctive action charging a foreign firm and two individuals with illegally selling off-exchange futures contracts and fraud in connection with those sales. The federal district court issued an order freezing the firm's United States assets and granting Commission access to the firm's books and records. Subsequently the court issued a preliminary injunction continuing the relief.

- A federal district court entered an order of disgorgement against two individuals requiring them to disgorge $1,995,120 to a previously appointed receiver for distribution to defrauded investors.

- Two injunctive actions separately charging two firms with fraud in connection with the offer and sale of dealer and exchange traded options. The complaints allege that the firms misrepresented the likelihood of profits, the risk of loss, and their expertise. Approximately 85 percent of the firms' customers lost money while trading.

- An injunctive action charging a firm and four individuals with fraud in connection with the sale of exchange traded options. The day after the complaint was filed, the federal district court issued an order protecting all books and records. The court subsequently issued a preliminary injunction.

- Two injunctive cases filed separately with the state of California against two firms alleging the illegal sale of off-exchange futures contracts and fraud in connection with the sale of those contracts. Preliminary injunctions have been issued in both cases, freezing all assets, protecting books and records and appointing receivers. One receiver has collected

$1 million and the other $496,725 for distribution to defrauded customers.

- A federal district court ordered all five defendants who previously were found to have sold off-exchange futures and options contracts to make restitution of $15,018,00 to their defrauded customers.

- Two firms and six individuals were permanently enjoined from offering and selling foreign commodity options and foreign futures in the United States. Four of the individuals consented to disgorge over $275,000.

Administrative Proceedings: In the administrative forum, the Commission's cases filed and settlements reached during the first nine months of FY 1989 include:

- A case charging 22 floor traders on the CME with executing non-competitive trades, of the nature of wash and fictitious sales thereby causing non-bona fide prices to be reported.

- A case charging three firms and five individuals with executing fictitious sales, noncompetitive trades and trades which caused non bona-fide prices to be reported. Two firms and four of the individuals also were charged with accommodation trading and one firm and two of the individuals were charged with engaging in wash sales. In settling the case, the respondents agreed to pay civil monetary penalties totalling $527,500.

- A case charging a futures commission merchant and four individuals with violating the anti-fraud, competitive trading, recordkeeping and supervision provisions of the Act and Regulations. The charges stem from an allegedly fraudulent trade allocation scheme.

- A case charging two firms and three individuals with fraud in connection with the offer and sale of commodity futures contracts and with failure to supervise. One firm and one individual also were charged with various recordkeeping violations.

- A case charging a firm, three of its corporate affiliates and five individuals with various violations of the Commission's registration, anti-fraud, trade practice, recordkeeping and reporting provisions. In settling the case, the firm and its affiliates agreed to pay a civil monetary penalty of $4 million.

- Separate cases charging eight traders with fraud and non-competitive trading. In settling the cases, the respondents agreed to sanctions which included registration revocations, where applicable, and trading suspensions.

- A case charging two firms and three individuals with fraud in connection with the offer and sale of commodity options contracts and with failing to supervise the one firms' salespeople.

- A case charging five individuals with executing wash and fictitious trades, non-competitive trades and trades which resulted in non bona-fide prices being reported. Along with three others, the five also are charged with violating the speculative position limit for the contract involved.

Relief Obtained: In administrative proceedings completed during the fiscal year, civil penalties totalling $7,100,400 were imposed, of which $1,230,000 is subject to appeal. Sanctions and other relief obtained in civil injunctive and administrative cases during FY 1989 were as follows:

o	Persons preliminarily enjoined:	20
o	Persons permanently enjoined:	29
o	Persons against whom cease and desist orders were entered:	68
o	Persons whose registrations were either suspended, denied or revoked:	29
o	Persons prohibited from trading:	35
o	Number of persons subject to civil penalty assessments:	47
o	Dollar amount of civil penalty assessments:	$7,100,400

In addition, as a result of the Commission's civil injunctive actions, approximately $2,168,505 in customer funds and other assets have been placed under the protection of a receiver for eventual distribution to customers.

Assistance in Criminal Actions: In addition to bringing civil and administrative proceedings on behalf of the Commission, the enforcement staff provided expert investigative and technical support to United States Attorneys' offices for the investigation and prosecution of criminal violations of the Commodity Exchange

Act (CEA) and other statutes. During FY 1989, such cases included:

- The indictment of eighteen former APs of an FCM on 192 counts of wire fraud, mail fraud, racketeering and racketeering conspiracy.
- The indictment of an individual on charges of commodity pool fraud and mail and wire fraud stemming from the fraudulent operation of a commodity pool.
- The conviction of an individual on two counts each of mail fraud and tax fraud. The defendant was sentenced to twelve years imprisonment and ordered to make restitution to defrauded investors.
- The indictment of three individuals on 29 counts of conspiracy, mail and wire fraud, and commodities fraud.
- The indictment of 46 individuals on charges of commodity fraud and mail and wire fraud based on trading activities on the floors of various exchanges.
- The conviction of four individuals on four counts of conspiracy and eight counts of wire fraud. The defendants received sentences ranging from five years probation to six years imprisonment and were ordered to pay a total of $516,650 in fines.
- The conviction of four individuals on 11 counts of mail fraud, four counts of embezzlement, 2 counts of tampering with witnesses and 1 count of futures fraud. The defendants received sentences ranging from one to ten years imprisonment and were ordered to make restitution of over $4,900,000.

Planned Activities (FY 1990)

During FY 1989, the Division opened more investigations than anticipated, creating a corresponding increase in the number of pending investigations. Moreover, the Division has made a substantial commitment of its staff to cooperative enforcement matters. Staff assigned to such matters are unavailable to the Division's civil investigations and litigation. Nonetheless, the Division has continued to face demands for resources in ongoing and newly filed cases. Due to cuts in the FY 1990 Commission budget, the Division will receive only one new staff year to address these needs.

As a result of these factors, the Division anticipates that ongoing matters will require the commitment of substantial resources in FY 1990 which will greatly restrict its ability to either open or complete new matters. Accordingly, the Division estimates that it will open 54 cases and complete 53 cases during the fiscal year. The Division also expects to open 70 investigations and complete 64. These estimates assume that no series of events in the futures markets will occur which by their combined magnitude require commitments of an extraordinary amount of investigative resources. In the past, just one investigation has consumed as much as 15% of overall Division resources. When the Commission moves quickly to place a financially troubled firm in receivership or to halt an ongoing fraud, staff must be transferred from ongoing investigations, deferring their completion.

Given its essentially unchanged staff size for FY 1990, the Division's activities and priorities will be generally unchanged. The Enforcement staff will continue to focus its efforts on Commission registrants -- those individuals and firms over whom the Commission has exclusive jurisdiction -- especially in the areas of customer fraud, trade practices, and market integrity. The Division's efforts in this area will be assisted by the use of the Commission's computer system for trade practice investigations. This system aids in detecting patterns of trading which might indicate illegal trading schemes and permits the staff to undertake large, sophisticated analyses of trading activity more efficiently than through manual techniques. The additional trade timing data available as a result of amendment to Commission Regulation 1.35(g) has further enhanced the use of the system. The Division also has increased its use of microcomputers to assist in data analysis and litigation support. However, automation cannot result in labor savings in enforcement to the same extent possible in other areas of Commission activity such as financial management and market surveillance. Enforcement matters involve unique sets of facts that must be examined, and require particularized judgments by enforcement lawyers and investigators. The actual presentation of evidence at trial and other litigation tasks cannot be automated. Thus, increases in enforcement work loads will continue to require commensurate staff increases.

Through participation in an inter-agency Securities and Commodities Fraud Working Group, and through its contacts with the Department of Justice and United States Attorneys, the Division will continue to assist and encourage federal criminal prosecution of commodities fraud in appropriate circumstances. The staff also will continue to offer its assistance to state law enforcement officials through seminars and cooperative enforcement efforts.

The Division anticipates new enforcement investigations and cases will be opened involving foreign activity given the internationalization of futures markets and the Commission's adoption of rules governing foreign futures and options. The Division has experienced an increase in instances of cooperation with foreign governmental authorities and anticipates that in FY 1990 further discussions will be undertaken with the Commission's foreign regulatory counterparts with a view toward regularizing the avenues of communication and assistance available.

Impact of the Current Level (FY 1991)

An enforcement program must maintain a credible presence in each of the principal areas of illegal activity and, at the same time, be able to focus additional resources when needed in areas of particular concern. Cases and investigations should be conducted with a view toward concluding them within a meaningful period after the conduct in question occurred.

At the current level, the Division cannot consistently implement this approach. Division attorneys and investigators are often required to shift the focus of their efforts in response to external factors such as market emergencies and court schedules. There is insufficient staff to maintain consistently aggressive investigations and prosecutions of both off-exchange boiler rooms and on-exchange violations while continuing cooperative enforcement efforts. In particular, the Division cannot devote sufficient resources to complex trade practice matters and cases involving fraud by introducing brokers, futures commission merchants, commodity pool operators and commodity trading advisors. Particularly given the increase in pending investigations during FY 1989, as well as the resources assigned to ongoing cooperative enforcement matters, at the current level the Division will be unable to prosecute additional cases or investigations as aggressively.

Justification of the Request (FY 1991)

The addition of 23 staff years will allow the Commission to increase resources in the trade practice area, including the Chicago and New York regional offices, to address the overall increase in the Division's work load, and to focus on areas exhibiting the strongest resource needs. A portion of this increase will compensate for requested staff increases that could not be implemented in FY 1990. In order to establish a direct Division of Enforcement presence on exchange floors, 5 of these additional Enforcement staff-years will conduct floor surveillance and work on associated enforcement investigations and litigation.

Based on past experience and recent trends, the Commission anticipates increased resource needs in the following areas:

Trade Practice: The investigation of potential trading abuses such as wash trading, accommodation trading, and fictitious sales is time consuming. Investigators and attorneys typically must assemble and painstakingly review a large volume of trading records. Trade Practice cases are often built on evidence gleaned from large numbers of records, and prosecuting such cases similarly requires significant staff resources. The Division has noted a significant increase in staff time in this area during the last two fiscal years. Assigning adequate staff resources to this area will require additional staff to maintain the Division's activities in other areas.

Introducing Brokers: The introducing broker category of registrant was created as a result of 1982 amendments to the Act. There are presently over 1,700 registered introducing brokers. The Division anticipates that the number of introducing brokers will result in the commitment of additional resources to this area. Indeed, the time spent investigating and prosecuting alleged fraud by introducing brokers increased by approximately four staff years from FY 1987 to FY 1989.

Cooperative Enforcement: The Division has increased the resources devoted to its wide range of cooperative enforcement activities. The Division will use a portion of the requested staff increased to support its continued involvement in cooperative criminal enforcement actions with United States Attorneys and the Department of Justice and its participation in the interagency Securities and Commodities Fraud Working Group. In addition, the Division anticipates a continued need for resources to attack unlawful sales practices, especially telemarketing fraud by boiler room operators. Here again, cooperative enforcement (including the filing of joint civil injunctive actions with states) is an integral part of the Division's arsenal and will continue to require staff resources.

MARKET SURVEILLANCE, ANALYSIS, AND RESEARCH

The Market Surveillance, Analysis, and Research program conducted by the Division of Economic Analysis is designed to keep markets free and competitive by detecting and preventing threats of price manipulation or other major market disruptions caused by abusive trading practices. Futures markets that are free of manipulation and other anticompetitive forces can most effectively perform their vital economic functions of price discovery and risk transfer. The program accomplishes its objectives by: (1) monitoring daily all actively traded futures and option contracts on 14 exchanges for market composition, the activity of large traders, key price relationships, and supply and demand factors; (2) analyzing the terms and conditions of proposed and existing futures and option contracts to assure that they are not inherently susceptible to manipulation or price distortion; (3) performing special economic studies and analyses to support the Commission's programs; and (4) providing expert advice on the economic impact of the Commission's regulatory policies and decisions.

Resource Changes (FY 1991)

The Commission estimates that an increase of $1,106,000 is required to maintain the Market Surveillance, Analysis and Research Program in FY 1991. The increase requested includes the costs related to eleven additional staff-years ($627,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($479,000). Total request for FY 1991: $7,225,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	94	102	113
Obligations (000):			
Comp/Benefits	$3,853	$4,619	$5,574
Other (Direct)	182	218	238
Other (Pro rata)	1,106	1,282	1,413
Total	$5,141	$6,119	$7,225

MARKET SURVEILLANCE

The primary objective of the Market Surveillance subprogram is to detect and prevent price manipulation, threats of corners, and other market disruptions. Specifically, the staff:

-- Reviews daily market developments in all actively traded futures and option markets, including foodstuffs, precious metals, interest rates, foreign currencies, petroleum products and stock indices, in order to detect and prevent manipulation and other market disruptions;

-- Maintains contact with exchange market surveillance staffs and appropriate federal agencies to share critical information, communicate Commission concerns, and coordinate surveillance activities;

-- Keeps the Commission informed, through weekly surveillance meetings, of significant market developments and potential problems that may require Commission action and provides the Commission with special reports of significant market events for Commission review and action;

-- Enforces the Commission's speculative position limits and reviews exchange rule enforcement programs regarding speculative limit rules;

-- Monitors trading for noncompetitive and abusive practices which tend to impair the market's functions of risk transfer and price discovery;

-- Assists the Division of Enforcement in the investigation and prosecution of suspected violations of the Commodity Exchange Act; and

-- Collects, verifies and processes essential market data on open interest, prices, and large traders' activities.

Resource Changes (FY 1991)

The Commission estimates that an increase of $747,000 is required to expand the Market Surveillance subprogram in FY 1991. The increase requested includes the costs related to nine additional staff-years ($404,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($343,000). Total request for FY 1991: $5,078,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	70	74	83
Obligations (000):			
Comp/Benefits	$2,700	$3,249	$3,872
Other (Direct)	122	152	168
Other (Pro rata)	824	930	1,038
Total	$3,646	$4,331	$5,078

Accomplishments (FY 1989)

The Market Surveillance subprogram is based on daily monitoring of all active markets. In addition to reviewing daily reports on the activities of large traders, surveillance economists monitor cash prices, crop, storage and transportation reports, political and economic events, and other factors to detect and prevent abusive trading practices. Large traders are contacted frequently to obtain current information on their positions, delivery intentions and strategies. Unusual trader activities, short supply indications, or abnormal price relationships among cash, futures and option markets receive immediate analysis from surveillance economists. These economists work with their exchange counterparts to share information and to advise traders and brokers of their responsibilities for assuring an orderly liquidation.

Congested market conditions developed in several markets in FY 1989. In particular, a tight supply situation in soybeans caused the spot May and July 1989 contracts to move to unusually large premiums to deferred months. Surveillance staff maintained close contact with exchange officials and with large traders and carefully examined the actual hedging needs of several traders during these congested liquidations. As an additional regulatory tool to deal with threatened congestion in old crop grain and soy-complex futures, the exchange, through an emergency action in late May 1989, instituted exchange speculative position limits parallel to Federal limits in all of its agricultural futures. In a subsequent emergency action, on July 11, 1989, the exchange ordered a scheduled liquidation of the largest positions in the July 1989 soybean futures. This exchange action was taken pursuant to rules of the exchange and is consistent with the exchange's responsibilities. The rules permit the exchange to institute timely remedies whenever they believe an orderly liquidation of a contract is threatened. The Commission also modified the hedge exemption of the largest long trader. After the emergency, Surveillance staff assisted in the Commission's review of the action and in responding to congressional inquiries regarding it.

The stock index futures and option markets were markedly less volatile in FY 1989 than in the previous year. Nevertheless, surveillance staff were involved in several areas in order to improve the regulatory framework in these markets. For example, surveillance staff monitored the implementation of "circuit breaker" rules in the stock and stock index futures and option markets. These rules have established coordinated procedures for temporary halts in trading in stock and stock index futures and option markets when prices move by predetermined amounts. Surveillance staff also monitored a recently-installed hotline which provides a direct linkup among officials at all stock and stock index futures and option exchanges. This communication system facilitates the flow of prompt and accurate information among all exchanges of any self-regulatory initiatives taken during periods of market stress.

The June 1989 S&P 500 stock index futures contract maintained unusually high open interest into its expiration. Surveillance staff intensively monitored this expiration and shared surveillance information with the Securities and Exchange Commission staff. Although there was unusually high trading volume on the New York Stock Exchange on the morning of the major futures contract settlement, this trading did not lead to price volatility.

The tightness in the copper market, which began in FY 1988, continued into FY 1989. Low domestic and international copper supplies caused continued price volatility. The surveillance staff maintained close contact with exchange officials and with large traders as each expiration month progressed. Intensive and coordinated activities by exchange and CFTC surveillance staff effectively dealt with several congested contract liquidations, avoiding the need for emergency action.

During FY 1989 the role of dual trading in futures and option markets was called into question as a result of the cooperative investigation into floor trading practices by the CFTC and the U.S. Attorney's Office in Chicago. Division staff designed and conducted a study of the scope of dual trading across markets and its potential impact on market liquidity.

The Surveillance staff also participated in the reviews of two exchange surveillance and speculative limit enforcement programs. The findings of these reviews and the staff's recommendations for improvement were presented to the Commission and published.

The Commission approved two significant rulemaking initiatives in FY 1989 pertaining to Market Surveillance. Effective December 1988, the Commission amended its exemptions to speculative position limits to include spread or arbitrage positions, not to exceed twice the single month position limit, between single months of a futures contract traded on the same board of trade outside of the spot month, in the same crop year.

At the same time, the Commission also modified its aggregation policy for positions of commodity pools which have multiple, independent, unaffiliated commodity trading advisors. This exemption permits commodity pool operators to apply to the Commission for a higher speculative position limit on a case-by-case basis. Under the proposal, the commodity pool operator has to demonstrate that trading for its accounts is controlled by independent account controllers.

During FY 1989 the Market Surveillance staff, working closely with staff of the Office of Information Resources Management, enhanced its monitoring of Commission and exchange speculative limits by extending its automated speculative limit checks to commercial traders. This involved adding cash position information obtained from series '04 reports to the computer data base, so that cash, futures and options positions of large commercial traders could be related to an array of Commission and exchange speculative limit rules. This allows for more effective monitoring of all positions with respect to enforcing existing limits and reduces significantly the number of reports that must be checked manually.

Planned Activities (FY 1990)

Market surveillance will be conducted on more than 130 actively traded futures and option markets in FY 1990. Total trading volume is expected to increase by about 12 percent. The increased surveillance workload will be accommodated with a modest staff increase and through increased reliance on expanded computer support for data compilation and analysis. However, the staff will be increasing its trading floor surveillance activities in conjunction with the other divisions to deter abuses in trade execution practices. Some of the increased staff time devoted to floor surveillance will be at the expense of other routine surveillance practices.

The Surveillance staff will monitor all markets for indications of price manipulation or market disruption and prepare approximately 2,700 weekly surveillance reports on expiring contracts. This will require processing approximately 780,000 reports. The Surveillance staff also plans to conduct 190 audits of futures commission merchants and clearing members for compliance with Commission reporting regulations and to conduct 75 special surveillance-related analyses. Suspected violations of the Commodity Exchange Act discovered by Surveillance staff will be referred to the Division of Enforcement, and Surveillance staff will assist in the investigation and prosecution of cases where economic analyses or market expertise is required. In addition, the Surveillance staff expects to conduct two reviews of exchange rule enforcement programs regarding market surveillance or speculative limits in cooperation with the Division of Trading and Markets.

The Surveillance staff will participate in a study of stock market volatility and the relationship of index arbitrage and circuit-breaker rules to volatility. The Surveillance staff also will review survey data on trading by commodity pools, as part of a study designed to provide a factual basis to reconsider the Commission's policy with respect to aggregation of commodity pool trading.

Impact of Current Level (FY 1991)

Total volume of futures and option trading is expected to rise from 360 million contracts in 1990 to 393 million contracts in 1991, an increase of about 9 percent. The introduction of computerized trading of futures and options, as is currently proposed by several exchanges, may if successful cause a faster growth rate. The total number of futures and option contracts being traded should increase to over 140 by FY 1991.

The Market Surveillance subprogram faces significant challenges brought about by added volume, new and different market instruments, and greatly expanded international participation and market influences. The trend toward internationalization of U.S. commodity markets, through the introduction of new contracts, intermarket linkages, extended trading hours, and computerized trading, is expected to add new complexities to the surveillance process.

In addition, the Commission has determined that its staff should initiate a new program of intensive, in-person surveillance of trading practices on all exchange floors. At current staffing levels, all of the routine surveillance activities cannot be accomplished along with the new floor surveillance responsibilities. Floor surveillance is a manpower-intensive activity that requires additional trained staff to detect and prevent trading abuses.

Finally, the staff plans to complete several studies in FY-1991 assessing several regulatory initiatives, including expanding the exemptive classes within the Commission's aggregation policy and re-examining the extent and nature of dual trading in light of certain regulatory proposals. These studies, and any regulatory relief that could derive from their completion, would have to be delayed.

Justification of Request (FY 1991)

The requested increase of nine staff-years will enable the Market Surveillance subprogram to conduct routine floor surveillance, keep pace with the continued growth of approximately ten contracts in the number of active markets being monitored, and complete necessary regulatory studies, including those relating to aggregation and dual trading. Coordinating with other divisions, the Market Surveillance staff will be responsible for covering a significant portion of the direct Commission floor surveillance of all exchanges to detect and deter trade practice abuses. This floor surveillance will deter these abuses through increased referrals of potential trading infractions for investigation and possible prosecution. The Market Surveillance staff's floor surveillance will be part of the planned and coordinated floor surveillance program of the Commission.

Additional Market Surveillance economists also are needed to maintain a high degree of specialization in assigned markets to analyze potential market problems early enough to implement preventive actions. The increased internationalization of markets, plus the addition of new and complex futures and option contracts, is making this task increasingly difficult. Adding additional contracts to the burden of the existing Surveillance staff would diminish the comprehensive and detailed knowledge of futures and cash market practices required of successful Surveillance economists. It also would prevent the Surveillance staff from completing special regulatory studies that assist the Commission in formulating regulatory policy based on a quantitative analysis of our surveillance experience.

MARKET ANALYSIS

To ensure that futures and option markets operate efficiently without market disruption or price manipulation, the Market Analysis staff reviews each application for contract market designation, as well as proposed changes of economic significance to existing contracts. Deficiencies in the terms and conditions of futures and option contracts increase the likelihood of cash, futures, or option market disruptions and also decrease the economic usefulness and efficiency of a contract. To avoid these consequences, the Market Analysis staff analyzes the following issues for each application and proposed rule change that it reviews: (1) conformity of contract terms and conditions with commercial practices; (2) adequacy of deliverable supplies or, if applicable, cash settlement procedures; (3) commercial usefulness of the contract; and (4) public interest implications, as appropriate. In addition, the Market Analysis subprogram has responsibility for review of the terms and conditions of applications for the registration of leverage commodities.

Resource Changes (FY 1991)

The Commission estimates that an increase of $71,000 is required to maintain the Market Analysis subprogram in FY 1991. The increase requested will maintain the FY 1990 staffing level and provide for a share of the Commission's anticipated increase in operating expenses for FY 1991. Total request for FY 1991: $1,076,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	14	14	14
Obligations (000):			
Comp/Benefits	$661	$ 789	$ 859
Other (Direct)	35	40	42
Other (Pro rata)	164	176	175
Total	$860	$1,005	$1,076

Accomplishments (FY 1989)

During FY 1989, the Market Analysis subprogram completed the economic reviews of 14 applications for new futures contracts, three applications for new option contracts, and 115 rule amendment packages for existing futures and option contracts.

The Commission approved several futures contracts in foreign stock indexes and bonds geared to the specialized needs of international portfolio managers and other institutional investors in equities and fixed-income securities traded overseas. Such contracts approved in FY 1989 include: the Chicago Board of Trade's (CBT's) long-term United Kingdom gilt, long-term Japanese government bond and Japanese stock-index contracts; the Chicago Mercantile Exchange's (CME's) Nikkei stock average and Europe, Australia and Far East (EAFE) stock-index contracts; and the Coffee, Sugar and Cocoa Exchange's (CSCE's) International Market Index stock-index contract.

In addition, during FY 1989 the Commission approved several other innovative financial futures contracts geared to specialized hedging needs of financial institutions. The Commission approved three futures contracts based on cross-currency Euro-rate differentials--i.e., the CME's Japanese yen, British pound sterling and West German deutschemark Euro-rate differential (DIFF) contracts. These three contracts were designed to provide hedging opportunities for international financial institutions which have assets and liabilities denominated in both U.S. dollars and yen, pounds sterling or deutschemarks. Other new financial futures contracts approved in FY 1989 include the CME's and New York Cotton Exchange's (NYCE's) Federal funds rate futures contracts, which provide hedging benefits to Federal funds traders, bank asset/liability managers, and short-term borrowers and lenders.

In addition, in FY 1989 the Commission approved futures contracts for the Amex Commodities Corporation in ten-year U.S. Treasury notes, the NYCE in two-year U.S. Treasury notes, and the New York Mercantile Exchange (NYMEX) in residual fuel oil. The three option contracts approved in FY 1989 include two options on futures contracts--the CME's Nikkei stock average option, and the MGE's European exercise option on hard red spring wheat. In addition, the Commission approved an option on a physical commodity--the CME's option on physical British pounds sterling.

During FY 1989, the staff completed the economic reviews of 89 rule amendment packages for existing futures contracts, and 26 rule amendment packages for existing option contracts. These rules included proposals approved by the Commission to establish coordinated price-fluctuation-limit and trading-halt provisions (circuit breakers) for all listed stock-index futures and option contracts. These circuit-breaker provisions were submitted by the exchanges in response to the recommendations of the Presidential Working Group on Financial Markets, which was established to study the complex issues raised by the stock-market break in October 1987. The proposals approved by the Commission were part of a coordinated effort undertaken by domestic markets for equities and equity-related products to deal with large, rapid market declines that threaten to create panic conditions.

Other changes to reactivate existing, but inactive, futures contracts were approved in FY 1989. The inactive contracts amended include the CBT's short-term U.S. Treasury note contract, the New York Futures Exchange's Treasury bond contract, the CME's London-delivery gold contract, and the Kansas City Board of Trade's grain sorghum futures contract. The Commission also approved amendments to the quality specifications for the NYMEX's unleaded gasoline contract to reflect recent changes in air-quality standards, and it approved changes to the NYCE's frozen concentrated orange juice futures contract regarding load-out requirements.

The staff continued to achieve a high level of efficiency in processing designation applications and rule changes because of the refinement of procedural changes initiated in previous years. These revised procedures include emphasis on both formal and informal meetings with relevant exchange officials to discuss deficiencies in submissions, expanded coordination with other agencies to resolve issues more quickly, and continued use of delegated authority for the approval of a large proportion of rule changes.

Planned Activities (FY 1990)

During FY 1990, the Market Analysis subprogram expects to complete the economic reviews of 14 futures and four option contracts and 118 rule amendment packages for existing futures and option contracts. The reviews require significant resources and must be completed within statutory time frames established by the Futures Trading Act of 1982--one year for futures or option contracts (unless the Commission notifies the exchange in writing of material deficiencies, which tolls the one-year period) and 180 days for rule changes.

The Market Analysis subprogram started FY 1990 with a workload of 21 pending applications for futures and option contracts as well as several complex rule changes. The Commission also expects about 18 additional futures and option contracts and 118 rule changes to be proposed by exchanges in FY 1990. The projections are based on the historical rate of submission of designation applications and indications that the exchanges will continue to make innovative proposals, particularly with regard to contracts based on foreign stock indexes and fixed-income securities issued by foreign governments. These projections also reflect the trend toward updating existing futures contracts to conform with current cash market practices.

The same staffing level in FY 1990 should permit the Market Analysis subprogram to continue to provide careful and timely analysis of proposed new contracts and rule changes aimed at detecting flaws which could result in market congestion or price distortion. In view of the current backlog and projected workload, there will be a carryover of a portion of the FY 1990 submissions to FY 1991. By effectively utilizing resources, the staff expects to meet the new workload and make progress reducing the backlog in FY 1990 with no further increase in staffing.

Justification of the Current Level (FY 1991)

The rate of submission of applications for contract designation is expected to continue at a high level through FY 1991 due, in part, to exchanges' continuing interest and competitiveness in developing novel financial futures and the tendency to establish option contracts on new futures that have traded successfully for a period of time. The staff expects that 19 futures and option application reviews will be completed during FY 1991, based on the historical rate of submissions and the backlog from FY 1990. Futures applications are expected to continue to include a number of innovative contracts that require significant staff resources for the resolution of novel and complicated issues. Such contract proposals frequently require coordination with other federal agencies and, in some cases, agencies of foreign governments. In addition, the staff projects 121 rule changes for review during FY 1991, including a number of significant changes to existing rules.

At the current level, the staff will be able to complete the review of new contracts and rule change packages in FY 1991 within the statutory time limits and will be able to perform the necessary level of review of contract terms and conditions. The staff also expects to continue to make progress in reducing the backlog of pending designation applications.

MARKET RESEARCH

The Market Research staff performs several major functions:

- Provides economic analyses for enforcement investigations and expert testimony for litigation.
- Performs research on, and evaluation of, the economic functions and pricing efficiency of the futures and option markets, such as the evaluation of the option pilot program prepared for the Congress.
- Conducts special market studies, such as the congressionally requested study of the effect of trade embargoes on hedgers and the analysis of the effects of futures price limits for the Working Group on Financial Markets.
- Provides support for other programs or subprograms, such as assisting the Market Analysis subprogram with reviews of option designations and rule changes and the Financial Audit subprogram in the Division of Trading and Markets with analyses of net capital and margin rules.
- Conducts economic research relevant to the formulation and implementation of Commission policy with regard to such issues as the development of the regulatory structure for leverage contracts, dealer options, and options on physical and agricultural commodities.
- Provides technical support and assistance to other governmental agencies. Such activities have included staff support for the U.S.D.A.'s Agricultural Option Advisory Committee and expert advice to the U.S. Attorney's office in off-exchange fraud cases.

Resource Changes (FY 1991)

The Commission estimates that an increase of $288,000 is required to fund the Market Research subprogram in FY 1991. The increase requested includes the costs related to two additional staff-years ($213,000) and a share of the Commission's anticipated increase in operating expenses in FY 1991 ($75,000). Total request for FY 1991: $1,071,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	10	14	16
Obligations (000):			
Comp/Benefits	$492	$581	$843
Other (Direct)	25	26	28
Other (Pro rata)	118	176	200
Total	$635	$783	$1,071

Accomplishments (FY 1989)

During FY 1989, the Market Research subprogram conducted a survey of trading by commodity pool operators. The survey report is expected to be completed in FY 1990. In addition, the staff completed its study of an intraday analysis of liquidity and price volatility in the S&P 500 index futures markets.

The staff also performed an empirical analysis of the impacts of the dual trading system on market liquidity for selected financial and agricultural futures and options markets. In FY 1989 research staff completed studies on the effect of margins on stock market volatility, the basis relationships between stock and stock index futures prices, and the effects of the introduction of stock index futures on stock market volatility.

The Research Section also provided support for the development of Commission off-exchange releases through participation in the Off-Exchange Task Force. Staff members presented papers at various academic meetings, received acceptance of articles for publication in refereed publications, and served as referees for various journals.

Planned Activities (FY 1990)

Research staff will study the effect of changes in market microstructure on the liquidity of markets, support research required by the Presidential Working Group on Market Mechanisms regarding the intermarket effects of stock and stock index futures trading, as well as undertake studies of off-exchange instrument regulation, and the regulatory effects of the introduction of electronic trading systems. The research subprogram will provide economic advice and special project assistance to other divisions, offices and agencies.

In addition, Research staff will continue to provide support for contract designation reviews, new exchange trading-proposals, off-exchange instruments, and reviews of option margining and clearing proposals. The staff also planned to undertake more extensive reviews of the economic impact of regulations, but these plans will have to be scaled back due to the loss of one position.

Impact of Current Level (FY 1991)

During FY 1991 research staff will study the impact on futures and option market liquidity and efficiency of changes made pursuant to the Commission's regulatory program in 1989, particularly the impact of changes in dual trading procedures. The staff will also work on projects relating to intermarket coordination which come from the Presidential Working Group on Financial Markets. It is anticipated that a survey of a futures market sector will be undertaken and that a study of the pricing efficiency of electronic markets will be initiated during FY 1991. The research subprogram will continue to provide economic advice and special project assistance to other divisions, offices, and agencies, as well as support for contract designation, new exchange trading proposals, off-exchange instruments, option margining and clearing proposals, and the economic impact of regulations. Staff will study market microstructure and market performance issues arising from increased globalization of trading.

The impact of maintaining the FY 1990 level of staff would be to curtail or preclude: market-by-market review of the effect of changes in dual trading procedures; the investigation of the effects of globalization; and a significant proportion of the investigation of the performance of electronic markets.

Justification of Request (FY 1991)

The request for an increase of two staff-years in FY 1991 is necessary to enable the Research subprogram to respond to the increased requirement to analyze the regulatory impacts and the questions of appropriate market structure and market performance which will arise from the increase in the formal and informal relationships among markets around the globe and the advent of electronic trading. Changes in the Commission's regulatory program in FY 1989 will necessitate additional research staff capability in the area of market microstructure to identify and analyze those aspects of global trading and electronic markets which are related most importantly to liquidity and price efficiency of futures and option contracts. In addition, it is anticipated that staff will be required to undertake an analysis of the effect of changes in dual trading procedures as required on a market-by-market basis regarding the effect on liquidity and price volatility. Also, studies of the effects of market structure changes resulting from ongoing investigations of other trading practices will place additional demands on the microeconomic resources of the subprogram.

The Commission requires more empirical studies prior to determining an appropriate course of regulatory action. This research demand requires an increase in the subprogram's capabilities in the areas of industry and floor trading practices, economic theory, econometrics and statistics. The current level of expertise in these areas is sufficient only to maintain the current level of activity in the areas of market microstructure and trading behavior, econometric and statistical study design.

Thus, to meet the increase in demand for Research expertise in the expanding areas of the Commission's regulatory program the addition of two staff-years will be required.

CONTRACT MARKETS, REGULATORY DEVELOPMENT AND OVERSIGHT AUDITS

The Division of Trading and Markets (T&M), operates the Contract Markets, Oversight Audits, and Regulatory Development program. The Division develops, implements, interprets and oversees enforcement of rules which are designed to protect customer funds, prevent trading and sales practice abuses, and assure the financial integrity of firms holding customer funds. In this connection, the Division monitors compliance activities of the designated contract markets and the National Futures Association (NFA). This program is designed to prevent and detect problems early so that steps can be taken to minimize their effects. When possible violations of the Act and Commission rules are uncovered in the course of its oversight activities, the Division refers such violations to the Division of Enforcement for further action and provides expert testimony and records analysis.

In addition, the Division reviews exchange rules and contract market designation proposals to ensure compliance with statutory requirements. Finally, it monitors the collection of civil penalties, performs fitness reviews for floor brokers, oversees the NFA's registration program, and handles registration exemption and relief requests.

Resource Changes (FY 1991)

The Commission estimates that an increase of $1,935,000 is required to maintain the Contract Markets, Oversight Audits, and Regulatory Development Program in FY 1991. The increase requested includes the costs related to 24 additional staff years ($1,194,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($741,000). Total request for FY 1991: $8,664,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff Years (FTE):	104	102	126
Obligations (000):			
Comp/benefits	$4,879	$5,150	$6,749
Other (Direct)	279	297	340
Other (Pro rata)	1,224	1,282	1,575
Total	$6,382	$6,729	$8,664

Contract Markets and Registered Futures Associations

The Contract Markets and Registered Futures Association subprogram conducts oversight of industry self-regulation. In particular, the subprogram assures that the rules and practices of the 14 exchanges and NFA are in compliance with the provisions of the Act and the rules of the Commission and are affirmatively enforced. All exchange applications for designation as a contract market and all exchange and NFA rule submissions are reviewed for compliance with the Act.

Subprogram staff conducts rule enforcement reviews which are targeted to particular activities within each self-regulatory organization's program and are based in part on direct surveillance of trading. In such reviews, the staff makes recommendations for actions by the self-regulatory organizations, and assesses the need for regulatory changes. In addition to these oversight activities, the staff conducts special studies such as the FY 1989 studies concerning dual trading and broker associations.

Resource Changes (FY 1991)

The Commission estimates that an increase of $1,147,000 is required to maintain the Contract Markets and Registered Futures Associations subprogram in FY 1991. The increase requested includes the costs related to 17 additional staff years ($836,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($311,000). Total request for FY 1991: $3,152,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff Years (FTE):	36	38	55
Obligations (000):			
Comp/Benefits	$1,323	$1,420	$2,340
Other (Direct)	96	107	124
Other (Pro rata)	424	478	688
Total	$1,843	$2,005	$3,152

Accomplishments (FY 1989)

During FY 1989, the staff devoted considerable resources to assessing exchange self-regulatory programs and analyzing related issues arising in connection with reauthorization and, in particular, press reports concerning a cooperative criminal investigation of floor trading practices on certain commodity exchanges. The staff prepared extensive responses to numerous inquiries by

Congressional committees concerning trading practices, exchange self-regulatory procedures, and the Commission's oversight role. The staff also sent detailed inquiries to all the exchanges concerning these matters. The staff analyzed the exchange responses, conducted independent studies on issues such as dual trading and broker associations, and prepared proposed regulations to address some of the issues which had been identified.

During FY 1989, the subprogram continued to fulfill its regular oversight functions. The staff recommended Commission approval of 790 rules or rule amendments submitted by the exchanges and NFA and reviewed 258 other exchange rules. These rules included several submissions that required extensive analysis such as the Chicago Mercantile Exchange's (CME) Globex system, the first electronic trading system approved under the Act, and the CME's SPAN margin system, a complex methodology for computing margin requirements on a portfolio basis. In addition, the staff prepared detailed Federal Register releases requesting comments on proposals to permit the futures-style margining of option premiums and the cross-margining of commodity futures and option positions with related security option positions held in different markets.

Staff also reviewed 17 applications for contract market designation, 14 futures and three options. Several of these contracts contemplated pricing and settlement in a foreign currency. In connection with these contracts, the staff prepared Financial and Segregation Interpretation No. 12, which allows customer segregated funds to be held overseas for the first time, subject to certain conditions.

The staff also conducted rule enforcement reviews of two exchanges' self-regulatory programs which covered trade practice surveillance, market surveillance, and disciplinary actions, as well as an evaluation of the exchanges' audit trail systems. The staff also issued two reviews regarding the arbitration programs at the NFA and at all exchanges.

Fifty-three trade practice investigations were concluded, resulting in nine referrals to the Division of Enforcement, and 25 referrals to the exchanges involving potential noncompetitive trading, dual trading abuses and other matters. These referrals each included multiple potential violations by multiple individuals and firms.

Planned Activities (FY 1990)

With the increase of two staff-years provided in the FY 1990 budget, the subprogram plans to conduct five rule enforcement reviews of exchange compliance programs and 70 trade practice investigations. These investigations will focus on high volume contracts when trading is volatile, on options trading, and on the operation of selected trading rules. The staff will continue to monitor the implementation and effectiveness of audit trail systems. Subprogram staff also will continue to review exchange and NFA arbitration programs to determine whether they meet the standards set out in the Act and Commission regulations and will prepare a report to the Commission regarding possible regulatory followup actions.

During FY 1990, the staff expects to review approximately 19 applications for contract market designation as well as approximately 820 rules submitted to the Commission by the exchanges and NFA for approval and 460 other exchange rules. The contract market reviews may include the application of the Twin Cities Board of Trade, a new exchange, which will require review of its entire rulebook. Other rules will include various developments in the CME's Globex system, rules implementing electronic trading on other exchanges, either through Globex or independently, rules implementing reforms developed in connection with evaluations by Commission staff and the exchanges of exchange self-regulatory programs, and, perhaps, rules related to futures-style margining and cross-margining.

The staff will continue to follow-up on issues raised in connection with reauthorization. The staff will finalize new regulations relating to dual trading, broker associations, maintenance and collection of trading cards, the placement of oral orders on exchange floors, and the eligibility of exchange members to serve on disciplinary committees. The staff also will continue its enhanced floor surveillance and continue its study of opening and closing procedures.

Impact of the Current Level (FY 1991)

At the current level, the subprogram will be unable to keep pace with its increasing responsibilities attributed to trade practice surveillance and related investigative activities. Recent events, including the ongoing reauthorization of the Commission by Congress and allegations of trade practice abuses arising out of the undercover cooperative criminal investigation of floor trading practices of certain exchanges, indicate that the subprogram must augment its oversight function through increased direct trade practice surveillance.

At the same time, however, the subprogram must continue to meet its increasing responsibilities in other areas. In that connection, the anticipated schedule of rule enforcement reviews of the exchanges' self-regulatory programs includes a growing number of areas of focus and amount of exchange activity which must be evaluated. Also, exchange and NFA rule submissions and proposed contract designations, which are subject to statutory deadlines, are expected to continue to increase in complexity with the creation of new products, development of new technology, growing internationalization of the markets, and greater competition from off-exchange instruments.

Justification of the Request (FY 1991)

The requested increase of 17 staff years for the subprogram, including seven staff years to be dedicated to floor surveillance and related activities, is essential to provide adequate resources for an increased Commission presence on the exchange floors and to review exchange programs to deter, and detect and investigate trade practice abuses. Such additional resources also will enable the subprogram staff to increase significantly the number of trade practice investigations and trade practice referrals to the Division of Enforcement and other appropriate authorities. Increased floor surveillance activity and other trade practice directed activities will be part of a planned and coordinated Commission-wide intensified surveillance presence. These objectives only can be realized through a significant additional resource allocation.

REGULATORY DEVELOPMENT AND REGISTRATION

The Regulatory Development and Registration subprogram develops, refines and interprets Commission regulations relating to registration, minimum capital, disclosure, foreign futures and options, and segregation requirements; oversees NFA's registration program; and administers the Commission's civil penalty collection program.

In the area of regulatory development, the subprogram's responsibilities include the formulation, modification and interpretation of the Commission's regulations and requirements for commodity professionals. The subprogram also responds to requests for exemptive relief from certain Commission regulations on a case-by-case basis and prepares advisories and other published statements to provide generalized guidance concerning the application of Commission regulations.

The subprogram is also responsible for the Commission's remaining registration functions. These responsibilities include oversight of the NFA's registration processing and fitness review programs as well as performing fitness review for floor brokers.

Finally, the subprogram is responsible for administering the Commission's civil penalty collection program.

Resource Changes (FY 1991)

The Commission estimates that an increase of $309,000 is required to maintain the Regulatory Development and Registration subprogram in FY 1991. The increase requested includes the costs related to two additional staff years ($165,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($144,000). Total request for FY 1991: $1,286,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff Years (FTE):	15	15	17
Obligations (000):			
Comp/Benefits	$749	$740	$1,019
Other (Direct)	43	49	55
Other (Pro rata)	176	188	212
Total	$968	$977	$1,286

Accomplishments (FY 1989)

During FY 1989 the subprogram developed new regulations or amendments to existing regulations in several areas, as well as various interpretative statements. These included amendments to rules governing arbitration to require that the list of qualified organizations to conduct arbitration proceedings of futures disputes which a registrant must provide to a customer include a registered futures association (i.e., NFA), and amendments to rules relating to leverage transactions to permit additional participation in the leverage business pursuant to a regulatory structure of direct supervision by a registered futures association under Commission oversight. The interpretative statements included a statement, issued simultaneously with a companion release of the Securities and Exchange Commission, to assist commodity pool operators in complying with requirements concerning the disclosure of past performance data and pool expenses.

In coordination with other divisions, the staff completed three major projects in the area of off-exchange commodity-related products. These included preparation of regulations providing an exemption from Commission rules for certain hybrid instruments with limited commodity option components based upon the limited nature of the option component and deference to other existing regulatory standards applicable to the noncommodity component of such instruments. In addition, the staff, in conjunction with other divisions, prepared an interpretative statement recognizing an exclusion from Commission jurisdiction for certain hybrid instruments and a policy statement with respect to certain swap transactions.

Substantial subprogram resources also were devoted to the review of petitions filed by foreign regulatory or self-regulatory authorities for exemptions from the requirements of the Commission's foreign futures and options regulations. Activities included analysis of the petitions and relevant regulatory provisions filed by nine foreign entities on behalf of their member firms or regulatees. Seven of those petitions were approved by the Commission, subject to certain conditions. In addition, the subprogram prepared recommendations for Commission disposition of petitions filed by two additional foreign exchanges seeking Commission authorization for option products on those exchanges to be offered and sold to U.S. residents. Three such petitions were approved by the Commission in FY 1988, subject to certain conditions.

Subprogram staff prepared approximately 225 written interpretations and responses to requests for exemptive relief from registration regulations, including six published opinions or exemptive letters. These letters dealt with issues such as exemption from associated person registration for certain corporate officers, dual and multiple affiliations of associated persons, re-registration requirements in the case of mergers and acquisitions, and registration requirements of foreign persons.

During FY 1989, subprogram staff, in coordination with other divisions and offices, also finished and delivered to Congress a report on leverage transactions mandated by the Futures Trading Act of 1986, which formed the basis for the rule amendments relating to leverage transactions referred to above.

During FY 1989, subprogram staff provided background analysis and staff support for the Commission's participation in the Presidential Working Group on Financial Markets and prepared a second update to the Interim Report of the Presidential Working Group on Financial Markets with respect to clearing and credit issues. Subprogram staff also recommended to the Commission proposed rule amendments relating to the risk disclosure requirements of futures commission merchants and introducing brokers.

In the registration area, the staff performed oversight activities including an on-site inspection of the NFA registration program encompassing the first in-depth review of NFA's fitness review program. In addition, the staff processed applications for renewal of registration for three leverage transaction merchants and 15 registration applications from associated persons of leverage transaction merchants. The Commission authorized NFA to perform this function on May 15, 1989 under Commission oversight. Staff also completed 159 investigations of floor broker and associated persons of leverage transaction merchant applicants or registrations leading to 23 applications being withdrawn or referred to the Division of Enforcement for denial or revocation (twice as many as the amount for FY 1988). Staff also processed 968 requests for withdrawal from registration.

Subprogram staff collected $5,658,000 in civil penalties in FY 1989 and $6,020,000 in new penalties became due during the fiscal year.

Planned Activities (FY 1990)

During FY 1990 subprogram staff will continue the development of rule amendments relating to the risk disclosure requirements of futures commission merchants and introducing brokers. Subprogram staff also plans to develop rules relating to the registration of floor traders, if Congress amends the Commodity Exchange Act as recommended by the Commission to provide enabling authority, and will continue to have a substantial role in the development of the Commission's regulatory framework with respect to off-exchange instruments. Subprogram staff may also need to develop additional new rules or rule amendments based on the outcome of the Congressional reauthorization process. Subprogram staff will also continue to provide interpretative guidance concerning regulations administered by the Commission and to provide case-by-case responses to requests for exemptions.

During FY 1990, subprogram staff will continue to support the activities of the Presidential Working Group on Financial Markets, particularly with respect to clearing and credit issues.

Subprogram activities in the foreign futures and option area are expected to increase, with the rapid growth of futures markets internationally and expanding interest in cross-border futures transactions.

In FY 1990, oversight of the NFA registration program will continue to be a significant subprogram activity and will include close monitoring of NFA enhancements to its fitness review program. Collections of civil penalties in FY 1990 are expected to amount to $1,500,000 and $2.5 million in new penalties will become due. Approximately 60 percent of the penalties to be collected relate to assessments which will first become due during FY 1990, and the remaining 40 percent relate to older penalties previously assessed.

The subprogram will continue to work in all of these areas in FY 1990. However, due to the fact that the subprogram will have one fewer staff year available in FY 1990 than it had in FY 1989, and the level of staff-years will be three fewer than the original estimate, progress in these areas may not be as rapid as it otherwise would be.

Impact of the Current Level (FY 1991)

Subprogram activities related to regulatory development are anticipated to increase significantly above the FY 1990 level. Without additional resources, the subprogram will be unable to fulfill existing responsibilities referred to above in addition to the additional requirements arising from developments in international markets, clearance and settlement systems, electronic trading and regulatory initiatives resulting from new statutory requirements.

Legislation currently under consideration by Congress will require the Commission to undertake several rulemaking proceedings pursuant to mandatory timetables and require the registration of floor traders as a new category of registrant. The legislation will also require the Commission to make certain reports to Congress within specified timetables, including a study of the competitive status of U.S. boards of trade in the world market. In addition, the subprogram will increasingly be called upon to support trade practice investigative actions, monitoring of the markets and new rules governing the markets. If subprogram resources were maintained at the FY 1990 level, the subprogram staff will be unable to continue to discharge its existing responsibilities and contribute to the new priorities established by Congress.

Justification of the Request (FY 1991)

The increase in resources requested for FY 1991 is necessary to complete on a timely basis required rulemaking and reports to Congress, additional legal support to market oversight programs, investigative activity, international issues, clearance and settlement systems and new initiatives in the area of electronic trading. Each of these areas will require commitment of substantial resources on a sustained basis. The requested resources will permit the subprogram to maintain current programs, such as monitoring of compliance with the foreign futures and option rules and oversight of NFA's registration program, plus these newly required additional responsibilities. Even with this increase, the subprogram will only have available one staff-year more than it actually used during FY 1989.

SALES PRACTICE AND MANAGED FUNDS

The Sales Practice and Managed Funds subprogram is an important part of the Commission's efforts to maintain public confidence in the markets by the prevention of fraudulent and misleading practices in the retailing of futures and options to the public and in the management of customers' accounts, including commodity pool accounts. The staff conducts sales practice rule enforcement reviews of the self-regulatory organizations to ensure that they are conducting acceptable sales practice audit programs of their members. The staff also conducts selected direct field audits of futures commission merchants to test the efficacy of self-regulatory organizations' audit programs and to address special concerns connected with its oversight of the operations of self-regulatory organizations' programs.

Subprogram staff reviews all commodity pool operator and commodity trading advisor disclosure documents to confirm compliance with the Commission's disclosure rules and, in the event of noncompliance, issues deficiency letters. This program also requires that the staff respond to numerous requests for interpretation of the rules for exemptive relief on behalf of commodity pool operators and commodity trading advisors. In volatile markets, the staff maintains contact with designated self-regulatory organizations to monitor problems as they arise. In this regard, the staff has developed procedures to obtain current information on the trading and financial status of futures commission merchants and certain large traders. In performance of its activities, the staff may identify potential rule violations for referral to NFA or the Division of Enforcement.

Resource Changes (FY 1991)

The Commission estimates that an increase of $171,000 is required to maintain the Sales Practice and Managed Funds subprogram in FY 1991. The increase requested includes the costs related to the two additional staff years ($60,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($111,000). Total request for FY 1991: $1,001,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff Years (FTE):	13	10	12
Obligations (000):			
Comp/Benefits	$ 660	$ 668	$ 811
Other (Direct)	34	36	40
Other (Pro rata)	153	126	150
Total	$ 847	$ 830	$1,001

Accomplishments (FY 1989)

The major objective of the subprogram in FY 1989 was the oversight of the industry-wide sales practice audit and surveillance program implemented by the NFA and the principal exchanges. NFA has delegated to three exchanges the futures sales practice audit and surveillance responsibilities for exchange member futures commission merchants, their branch offices and guaranteed introducing brokers. NFA retained responsibility for all other futures commission merchants, mostly non-exchange members, and their affiliates, in addition to all independent introducing brokers, commodity pool operators and commodity trading advisors. The undertaking of options sales practice responsibilities is a condition of designation of a contract market for options. During FY 1989 the staff conducted a review of the options or futures sales practice programs of two exchanges and NFA.

During the fiscal year, the staff also conducted reviews of the sales and marketing practices of 18 registered firms. The staff reviewed 3,440 disclosure documents filed by commodity pool operators and commodity trading advisors and issued 1,203 deficiency letters resulting from these reviews. Written interpretations totalling 111 were issued to commodity pool operators and commodity trading advisors. The staff also reviewed data relevant to an interpretative release, issued simultaneously with a companion release of the Securities and Exchange Commission, to assist commodity pool operators with requirements concerning the disclosure of past performance data and pool expenses.

Subprogram staff implemented a system to track disclosure documents filed by commodity trading advisors and commodity pool operators, which facilitated the review of documents within applicable time periods. This system also enabled the staff to effectively review amendments submitted subsequent to the filing of the disclosure documents. Additionally, the subprogram staff reviewed and compared the names of registered commodity trading advisors from records of the NFA to disclosure documents filed with the Division and forwarded a six month status filing letter with a reply form to 1,657 commodity trading advisors. In response to this letter, approximately 100 delinquent filings of commodity trading advisors were identified. The remaining recipients of letters indicated that they were either not managing or soliciting accounts, that they were exempt from filing under the regulations, or that they had terminated operations. These activities provided additional capacity to refer matters for further action to the Division's financial audit staff, NFA or the Division of Enforcement, as appropriate.

Planned Activities (FY 1990)

The staff will continue to assess the sales practice audit and compliance programs conducted by NFA and the exchanges to ensure that adequate coverage is being achieved without duplication of effort. The Division's current sales practice audit interpretation also will be evaluated and revised as necessary to provide further guidance to self-regulatory organizations in conducting sales practice audits and investigations.

The staff will conduct sales practice rule enforcement reviews of four sales practice audit and surveillance programs based on the volume of business conducted by the registrants assigned to individual self-regulatory organizations, and on the findings made and timing of previous reviews. Rule enforcement reviews also may be scheduled where there are indications of apparent deficiencies in a self-regulatory organization's program or where there are frequent violations on the part of registrants. The staff expects to conduct up to 10 direct sales practice audits to address special concerns and to continue its program of annual audits of leverage transaction merchants.

The staff will continue to receive and review a substantial number of disclosure documents and to respond to requests for interpretation of or exemption from applicable regulations.

Impact of the Current Level (FY 1991)

Maintaining the FY 1990 level of resources for FY 1991 will make it more difficult to conduct proper oversight over sales and marketing practices and the management of customers' accounts with the expected continuation and introduction of innovative trading products and marketing vehicles including foreign futures and options. In this connection, commodity pools are increasingly being sold to the general public, and retail options sales programs continue to be an appropriate focus of ongoing sales practice surveillance efforts.

Justification of the Request (FY 1991)

The proposed increase of two staff-years for FY 1991 is essential to provide the resources to maintain an effective oversight program of self-regulatory organizations' sales practice audit programs in view of the increase in the number of futures and options contracts offered and related trading strategies. The increase in resources will also permit selected audits of registrants to address any special concerns generated by new options and futures contracts as well as foreign options and futures products. Finally, the increased staffing level will permit the maintenance of an adequate program to review commodity pool operators and commodity trading advisors disclosure documents in light of the fact that the size and complexity of such programs continues to increase.

FINANCIAL AUDIT AND REVIEW

The Financial Audit and Review subprogram is critical to maintaining the financial integrity of the marketplace, the efficacy of clearing and settlement systems, and the financial stability of regulated firms.

Under this subprogram the staff conducts financial oversight reviews based on in-field audits of the programs by which the self-regulatory organizations directly monitor compliance by their member futures commission merchants with net capital, reporting, and record-keeping requirements and the financial integrity of such members, especially in volatile markets. Other activities include investigative audits or intensified oversight of futures commission merchants and other registrants in specific cases where financial rule violations are suspected, or where there is a financial emergency which threatens customers' funds. Subprogram staff provide expert testimony in enforcement cases, assist other law enforcement agencies in futures-related cases, and provide interpretations of the Commission's financial regulations. Finally, the staff assists in regulation of the managed funds industry by reviewing past performance tables filed by commodity trading professionals for accuracy and conformance with the regulations.

Resource Changes (FY 1991)

The Commission estimates that an increase of $308,000 is required to maintain the Financial Audit and Review subprogram in FY 1991. The increase requested includes the costs related to three additional staff years ($133,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($175,000). Total request for FY 1991: $3,225,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff Years (FTE):	40	39	42
Obligations (000):			
Comp/Benefits	$2,147	$2,322	$2,579
Other (Direct)	106	105	121
Other (Pro rata)	471	490	525
Total	$2,724	$2,917	$3,225

Accomplishments (FY 1989)

Improvements in assessing and controlling risk carried by member firms was a central focus by the audit staff during FY 1989. The staff assessed the exchanges' self-regulatory programs with respect to risk management, financial surveillance and financial issues and implications arising from trade practice and customer trading abuse. Also, the audit staff commenced development of a computer-based financial surveillance information system designed to integrate the review and assessment of futures commission merchant financial data with large trader position information and exchange clearing member position data from multiple markets. The system is being designed to calculate the potential for customer and firm losses based on various levels of market volatility. The new system will also include enhancements to existing systems to enable ongoing assessment of firms' aggregate financial exposure on a multiple market basis.

The staff completed two financial rule enforcement reviews of the audit and financial surveillance programs of the exchanges and their respective clearing organizations. The staff assisted a major SRO in taking action against a member firm suspected of serious violations on an international scale. Reports issued contained a number of recommendations for improvements and enhancements to the design and execution of the self-regulatory organizations' programs to monitor and enforce financial compliance by their member-firms. The reports included recommendations that the SROs should: conduct field audits of member-firms earlier when special circumstances warrant; verify the accuracy of large trader data reported by member-firms to the exchange; and expand their written programs to include existing procedures for monitoring maturing subordinated debt. The staff also recommended that one SRO share surplus and deficit margin data of its member-firms with the other commodity clearing organizations. The staff also monitored the commodity clearing organizations' implementation of a unified system to consolidate and to share financial surveillance and clearing information for dual-membership firms. This new system is expected to significantly enhance inter-market surveillance during volatile markets.

The staff also conducted 76 field audits and financial reviews of futures commission merchants, commodity pool operators and other registrants. These on-site audits are intended principally to test the efficacy of self-regulatory organizations' audit activities and, on a limited basis, to directly assess registrants' compliance with the Commission's financial regulations. These audits and financial reviews resulted in six referrals to the Division of Enforcement and the issuance of 153 warning and noncompliance letters citing registrants for apparent violations of the Commission's financial regulations.

The staff also completed financial audits of the three leverage transaction merchants to monitor their compliance with the Commission's net capital, cover, and segregation requirements.

During the year, the staff provided regulatory interpretations, answered requests for relief or exemption from the Commission's financial regulations, and provided accounting and financial expertise in support of enforcement investigations. Additionally, the staff directed special projects such as the development of financial reporting instruction books that provide guidance to futures commission merchants and introducing brokers in preparing the Commission's revised financial reporting forms.

Planned Activities (FY 1990)

The staff plans to conduct four financial rule enforcement reviews which will include monitoring the implementation of the exchanges' actions to reinforce existing financial integrity protections against volatile markets. The decreased staff level in FY 1990 will limit the subprogram's ability to dedicate staff to continue in-depth assessment of clearing and exchange financial surveillance programs in light of new products, international exposure and increased activity, and to coordinate with other relevant agencies.

On-site examinations will be conducted at approximately 45 futures commission merchants, 25 commodity pool operators and 20 other registrants such as commodity trading advisors and introducing brokers. In this connection, staff audit activities will be expanded to monitor compliance with the Commission's foreign futures and option regulations. Firms which solicit customers who wish to trade on foreign exchanges will be examined to verify that the firms are properly securing customer funds in separate accounts and that firms are complying with net capital requirements.

Interpretations and special projects will also focus on ways to improve financial surveillance during volatile markets. In this connection, the staff expects to implement a financial surveillance information system designed to integrate futures commission merchant financial data with large trader information and exchange clearing member position data. This computer-based financial surveillance system will enable the staff to retrieve futures commission merchant financial information in conjunction with information on positions held and to calculate the potential for customer and firm losses should the markets experience volatility. The financial surveillance system also will include enhancements to existing systems to produce aggregate inter-market position information and to enable ongoing assessment of firms' inter-market exposure. Enforcement support will continue but may be limited to major cases which require auditing and accounting expertise and financial document review.

Impact of the Current Level (FY 1991)

Because the increasing globalization of the financial markets has correspondingly increased the complexity of conducting adequate financial surveillance, the subprogram will have difficulty providing the necessary audit and financial surveillance coverage by continuing the level of resources proposed for FY 1990 during FY 1991.

As trading becomes more international, the number and types of instruments and accounts which must be audited increases, requiring a corresponding increase in resources. Due to the increasing complexity of risk management technology, the affiliation of securities and commodities exchanges, and the new international and domestic exchange links, the subprogram will be stretched to respond to the impact of internationalization on financial surveillance. Additionally, the staff will be unable to devote attention to financial issues and implications arising from trade practice and customer trading abuses.

Justification of the Request (FY 1991)

The Financial Audit and Review subprogram requests an increase of three staff years for FY 1991. Two additional staff years will be devoted to audit and regulatory activities addressing the financial implications of growing internationalization, the integration of the futures and option markets and resultant cross-margining programs, and increased oversight of markets, firms, and trade practices from a financial perspective.

In addition, the increase in resources will be used to consider how best to use the computerized financial surveillance information system, which will be fully operational in FY 1990, and other regulatory or systems improvements.

ADMINISTRATIVE MANAGEMENT AND SUPPORT

The Office of the Executive Director provides the Commission, the individual Commissioners, and the operating divisions with management and administrative services in support of agency objectives. The services include personnel, budget analysis, fiscal management, library support, administrative services and information resources management. In addition, the Office of the Executive Director coordinates short and long-range planning for the Commission.

Resource Changes (FY 1991)

The Commission estimates that an increase of $1,937,000 is required for the Administrative Management and Support Program in FY 1991. The increase includes the costs related to six additional staff-years ($205,000) and a share of the Commission's anticipated increase in operating expenses for FY 1991 ($1,732,000). Total request for FY 1991: $9,383,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	85	81	87
Obligations (000):			
Comp/Benefits	$3,479	$3,688	$4,129
Other (Direct)	2,777	2,739	4,167
Other (Pro rata)	1,001	1,019	1,087
Total	$7,257	$7,446	$9,383

Accomplishments (FY 1989)

During FY 1989, the Office of the Executive Director continued to focus on increasing automation to provide more effective service to the operating divisions and to management of the Commission's resources. In recognition of the importance of automation to the programs of the Commission, a separate section on the Office of Information Resources Management (OIRM) follows.

The Office of Budget and Fiscal Operations (OBFO), working in tandem with OIRM, converted to a new, off-the-shelf, fully integrated financial management system (FMS). This tool provides more effective processing of financial information, improves internal operations and eliminates labor intensive reconciliation efforts between the Commission's accounting system and several microcomputer-based subsidiary systems. In addition, this new financial management system provides new and timely financial information to all agency managers.

The Office of Administrative Services continued to increase its use of automation by developing an automated version of the Optional Form 11 for requesting documents from the Washington National Records Center. The staff also completed site selection, lease negotiation, office construction and relocation of the Kansas City Office and acquired additional space for the Los Angeles Office and the Washington headquarters. In addition, the staff conducted a records review of each Office and Division within the Commission and provided written recommendations to improve the records of each Office/Division and revised the Files and Disposition Handbook including a User Summary to assist Commission staff in better understanding and using the handbook.

During FY 1989, the Office of Personnel also continued to increase its use of automation. The Office installed new screens on its personnel/payroll system (PERMITS), which makes the system easier to use and reduces the opportunity for error. The staff also began using automated PC-based systems for tracking awards distribution and training requests. Also, the staff designed and distributed a PC-based form for performance appraisal.

To improve communications, the Office created an orientation briefing on personnel matters for new employees and developed an Employee Handbook, which provides a wide variety of information on personnel and administrative matters. In addition, the staff distributed information to managers on training opportunities and cooperative education programs, and on hiring handicapped employees. The office also continued to use its delegated direct hiring authority for students with a 3.5 or higher grade average for auditing and accounting jobs.

During FY 1989 the major accomplishment of the Library was the structuring and initial data input for the automated serials log-in system. This system gives the Library greater control over periodicals and more reliable statistics about the Library's activities.

Planned Activities (FY 1990)

During FY 1990, the Office of the Executive Director will continue to focus on improving the efficiency and effectiveness of its services and management of the agency's resources. FY 1990 will be the first complete year for the recently installed integrated financial management system which will result in better, more timely financial information. Single source data entry will improve accuracy of financial data and eliminate costly reconciliation efforts. In addition, the elimination of the Department of Treasury's payroll processing services, which is planned for FY 1991, will necessitate a resource intensive evaluation of other vendors to provide these services.

The Office of Administrative Services plans to install a desk top publishing system in the Reproduction Shop to assist in the design and printing of reports and other Commission documents and to install a PC-based space management system to provide the Commission with potential changes in floor plans and better utilization of existing space.

During FY 1990, the Office of Personnel plans to continue to focus on recruitment and retention, communication and automation. In the automation area, the staff will evaluate new personnel/payroll systems. Also, with an additional personnel management specialist on the staff, the Office will be able to devote more attention to creative solutions to recruitment and retention problems, including participating in job fairs and actively recruiting on college campuses.

It is anticipated that in addition to the services regularly provided, the Library will complete its project of putting its card catalog on line. Also, the tracking of reauthorization legislation will be a major focus of FY 1990. This will include compilation, organization, reproduction and binding of copies of the legislative histories for the Library and several other offices within the Commission.

Impact of the Current Level (FY 1991)

For the most part, the Office of the Executive Director will continue to carry out its essential functions at the current level. An area which may experience difficulty in providing essential support to the Commission is the Office of Budget and Fiscal Operations. The loss of an additional staff-year planned in FY 1990 will result in a slower than anticipated integration schedule for the Commission's automated subsidiary systems. Maximum utility of the potential benefits of the new financial system will not be achieved. Ongoing analytical work in the areas of travel, disbursements and staffing turnover will be effected negatively as well.

Justification of the Request (FY 1991)

The addition of six staff-years would allow the Executive Director's Office to support the Commission's programs in a more effective and timely manner. An additional staff-year in the Office of Personnel would allow the Office to adequately support the 66 staff-year expansion of the CFTC. Support could be provided in the establishment and management of positions in each division, the recruitment and hiring of qualified staff, and the timely processing of all personnel actions, including hiring, pay actions, benefit changes, etc. In addition, the additional staff person would serve as a valuable resource in providing both employees and managers with information on a variety of personnel topics, including benefits and retirement, promotion standards, employee rights and responsibilities, etc. The additional position would also provide support to ongoing communications projects, such as training for managers and employees. Five staff-years would be used by the Office of Information Resources Management to meet our ever-expanding needs in that area. The Commission also requests an increase of $1,430,000 to purchase a new mainframe computer. The need for these positions and the new mainframe computer is discussed in the section which follows.

INFORMATION RESOURCES MANAGEMENT

The Office of Information Resources Management provides critical support to all agency programs and operations.

Accomplishments (FY 1989)

The Office of Information Resources Management, in conjunction with the Office of Budget and Fiscal Operations, implemented the Commission's new off-the shelf integrated financial management system. Financial operations were converted to the new system in June 1989.

One of the major accomplishments of the year was the development of requirements for a financial surveillance system which will assist Commission staff in determining the financial losses from futures and options market positions. This system, which will include the ability to enter financial data from the Securities and Exchange Commission FOCUS reports, will be implemented in FY 1990.

In August 1989, the Commission's new long-range ADP plan was completed by the Office of the Executive Director. This plan identified systems to be developed and projected the resources required to implement the plan for the period from FY 1990 through FY 1993. Also included as part of this plan were:

1. An Office Automation and End User Computing plan which gives direction for the next five years;
2. A review of the Commission's Records Management Systems;
3. And an Information Resources Management Review which meets the OMB and GSA Federal Information Resources Management Review Program.

The growth in microcomputers projected in last year's budget request was realized. The number of microcomputers installed in the Commission at fiscal year end was 504. The office also continued to focus on the implementation of the Computer Security Act of 1987.

The office also assisted the Division of Trading and Markets in the review of new screen-based trading systems proposed by the industry. In conjunction with this, OIRM staff worked with both the Office of Management and Budget and the National Institute of Standards and Technology to ensure that computer security aspects of the proposed systems were adequately addressed.

Planned Activities (FY 1990)

OIRM will provide support for the Commission's increased reliance on end-user computing. There has been a dramatic growth in microcomputers and their use at the Commission. In FY 1984 the Commission had one microcomputer. This grew to 140 microcomputers by FY 1987, went over 500 in FY 1989, and will continue to grow in FY 1990. This growth in numbers has been accompanied by the implementation of local area networks in Chicago, Los Angeles, New York and Washington. The individual networks have been interconnected to form a Commission wide area network. OIRM had planned to install a local area network in Kansas City in FY 1990, but will be unable to do so with reduced funding.

Improvements to trade analysis software which assists in detecting potential trade abuses will continue in FY 1990 through the addition of new reports and the development of price change registers to reflect the times prices change in daily trading. This information will be used in trade practice investigations.

Refinements will continue to be made to the financial surveillance system as experience is gained using the system in FY 1990.

A planned effort to integrate capabilities to search varied collections of data related to formal complaints against individuals involved in the industry; including public complaints lodged with the Commission, complaints reported to the Commission by exchanges, and sanctions in effect resulting from complaints; will be delayed because of funding cuts.

Other systems development work will be undertaken by OIRM in accordance with priorities set by the Commission's ADP Steering Committee, within available resources.

Impact of Current Level (FY 1991)

Under the current staffing level, the Office of Information Resources Management does not have sufficient resources available to review exchange systems and test their ability to monitor for market abuses and illegal trade practices. Although there are currently Commission programs in place which evaluate the efficacy of exchange computer-assisted surveillance systems, it is important that those programs be augmented by assessments of computer hardware and software used in these systems.

In addition, the current level does not adequately support end user computing within the Commission. With an FY 1989 installed base of 504 microcomputers and more planned for installation in FY 1990, the number of staff available for general microcomputer support will be inadequate. Seven staff members now support all hardware, software, network, word processing, training and troubleshooting microcomputer problems throughout the Commission.

As projected in the Commission's five year ADP plan completed in July, 1989, under all scenarios used to project mainframe computer capacity requirements for the FY 1989 to FY 1993 five year period, an upgrade of the Commission's mainframe computer is needed in FY 1991 to support even the current level of operations. Without the funding necessary to procure a new mainframe computer system, the Commission will be unable to complete the daily market surveillance cycle within a single day without affecting daily operations of this and other essential Commission systems. Also, additional systems to detect potential trading abuses will not be developed if the computer cannot process the data.

Justification of Request (FY 1991)

Three staff years will be used for systems development and to assist in the review and audit the computer systems of the self-regulatory organizations, review screen based trading systems for which the Commission receives proposals, monitor the development and implementation of major industry computer system initiatives such as Globex and Aurora, and address the security requirements of industry and Commission systems.

Two staff years will be used to improve responsiveness in support to end user computing. Because of the growth of microcomputer use within the Commission, staffing to provide user training, hardware and software installation, troubleshooting and network management is already inadequate and will become more so with the installation of more equipment in FY 1990, as well as the increased support required by users as they achieve higher levels of sophistication in their use of the tools provided.

The request for $1,430,000 to purchase a new mainframe computer is required to allow the Commission to continue to monitor the daily activities of the futures and options markets and to meet the objectives of the recent five-year plan for ADP and data communications. Without this new computer, key analysis of potential trade abuses, financial condition and positions will not be possible due to the rapid growth in volume in the industry.

PROCEEDINGS

The Proceedings Program is operated by the Commission's Office of Proceedings under the administrative direction of the Office of the Executive Director. The Office of Proceedings is divided into two sections, the Complaints Section and the Hearings Section. The Complaints Section receives customer claims (called "reparations complaints") against persons or firms registered under the Commodity Exchange Act, prepares claims for forwarding to the Hearings Section and dismisses claims which are clearly outside the Commission's jurisdiction or which are pending in another forum. Judgment Officers in the Hearings Section decide customer claims in voluntary and summary proceedings and Administrative Law Judges conduct formal proceedings. Administrative Law Judges also decide enforcement cases brought by the Commission against persons or firms who have violated the Commodity Exchange Act or the Commission's rules and regulations.

Resource Changes (FY 1991)

The Commission estimates that an increase of $146,000 is required to maintain the Proceedings Program in FY 1991. The increase requested will maintain the funded FY 1990 staffing level and provide for a share of the Commission's anticipated increase in operating expenses for FY 1991. Total request for FY 1991: $2,025,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	27	28	28
Obligations (000):			
Comp/Benefits	$1,223	$1,331	$1,453
Other (Direct)	208	196	222
Other (Pro rata)	318	352	350
Total	$1,749	$1,879	$2,025

Accomplishments (FY 1989)

The number of complaints received by the Complaints Section in FY 1989 was 385. In addition, during FY 1989 the Office of Proceedings responded to about 15,000 phone calls, 1,100 written inquiries, and 800 walk-in requests, and sent out about 2,500 reparations brochures.

The Complaints Section forwarded to the Hearings Section a total of 385 complaints for voluntary, summary or formal adjudication during FY 1989. The Complaints Section ended 1989 with a workload of 56 complaints outstanding. The Complaints Section also supported activities of the Division of Enforcement by providing the Division with information on incoming complaints.

During FY 1989, the Hearings Section rendered initial decisions on the merits in 213 reparations cases. In addition, 18 reparation cases were dismissed for cause, 167 were settled and 30 were defaulted. At this rate of disposition, the Hearings Section was able to reduce its workload to 292 cases. With regard to enforcement cases, the Hearings Section began FY 1989 with a workload of 40 administrative actions. Thirty-eight actions were received during FY 1989. Of these 78 enforcement cases on the administrative law judges' dockets during FY 1989, 8 cases were settled, 30 decisions were issued and 40 actions were carried forward into FY 1990.

Both the Complaints and Hearings Sections were involved in the continuing publication of the Reparations Sanctions In Effect List and the Enforcement Sanctions in Effect List. The Reparations list, which is published annually and updated semimonthly, is a record of individuals and firms who have not paid reparations awards. The Enforcement list which is a record of individuals and firms who have enforcement sanctions such as trading prohibitions outstanding against them is published annually. These lists are available to the public and are distributed to the exchanges, the National Futures Association, the Futures Industry Association, the National Association of Securities Dealers, and the Securities and Exchange Commission for use in their compliance efforts.

Planned Activities (FY 1990)

During FY 1990, the reparations workload in the Complaints Section is expected to remain about the same. Given the rate of inquiries in FY 1989, the Office of Proceedings expects to receive about 15,000 telephone and 1,100 written inquiries, 800 walk-in inquiries, and expects to send out about 2,500 reparations brochures. It is estimated that the number of complaints received will be about 400.

The Hearings Section expects to have about 300 reparations cases pending at the end of FY 1990. It is estimated that more than 30 enforcement actions will be filed during FY 1990 creating a total workload of over 70 cases. The Hearings Section will be able to dispose of between 30 and 35 enforcement cases, resulting in approximately 40 cases being carried forward into FY 1991.

Justification of Request (FY 1991)

At the current level, the Complaints Section will continue to process complaints in a timely fashion, if the number of complaints and the number of public inquiries do not increase substantially.

The Hearings Section is expected to be able to manage both its reparations caseload and its enforcement caseload at the FY 1990 staffing level.

LEGAL COUNSEL

The Legal Counsel Program, operated by the Office of the General Counsel, provides the Commission, the individual Commissioners, and the Commission's operating divisions with legal services in support of agency objectives. These services include engaging in defensive, appellate, and amicus litigation; drafting administrative decisions; providing legal advice and support for the Commission's programs; drafting regulations; and interpreting the Commodity Exchange Act.

Resource Changes (FY 1991)

The Commission estimates that an increase of $266,000 is required to maintain the Legal Counsel Program in FY 1991. The increase requested includes two additional staff-years ($127,000) and provides for a share of the Commission's anticipated increase in operating expenses for FY 1991 ($139,000). Total request for FY 1991: $2,603,000.

	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Staff-Years (FTE):	33	33	35
Obligations (000):			
Comp/Benefits	$1,722	$1,850	$2,082
Other (Direct)	76	73	83
Other (Pro Rata)	388	414	438
Total	$2,186	$2,337	$2,603

Accomplishments (FY 1989)

Litigation. Legal Counsel's overall litigation caseload in FY 1989 was similar to that experienced in the previous year.

Legal Counsel's litigation generally can be divided into the appellate, district court and administrative areas. Turning first to appellate litigation, in FY 1989, Legal Counsel defended 23 appellate actions: five petitions for review of Commission administrative enforcement decisions, 13 petitions for review of Commission reparation decisions (a reduction by seven from the previous year) and five appeals from Commission-initiated district court injunctive actions. In addition, in FY 1989 Legal Counsel assisted the Solicitor General in defending a Commission action challenged in the Supreme Court, and defended the Commission's decision to reject an appeal of a disciplinary action taken by the National Futures Association.

In FY 1989, Legal Counsel's caseload in U.S. district courts increased above the levels in prior years. In FY 1989, Legal Counsel appeared on behalf of the Commission in seven district court actions. These cases principally arose from Commission enforcement actions and personnel matters. In addition, in FY 1989 Legal Counsel defended the Commission's right to conduct administrative enforcement proceedings against individuals engaged in voluntary bankruptcy proceedings, as well as an action by the Chicago Board of Trade seeking to overturn a Commission determination to modify a sanction imposed by the Board in a disciplinary proceeding.

Legal Counsel became involved in other district court and state litigation as well. For example, in FY 1989 Legal Counsel handled 27 matters in which parties in private litigation sought information from the Commission by serving subpoenas for the testimony of Commission staff and for the production of Commission records. As necessary, Legal Counsel sought to protect commercial and market sensitive information falling within the confidentiality provisions of Section 8 of the Commodity Exchange Act and to protect against disclosures which would impair Commission investigations, surveillance or enforcement efforts.

Another type of district court litigation involved bankruptcy proceedings of insolvent commodity brokers. Legal Counsel provided assistance to trustees and courts in such cases to insure that customers' funds received proper treatment under the Bankruptcy Code. In FY 1989, Legal Counsel handled 21 bankruptcy proceedings.

Legal Counsel also maintained its amicus curiae ("friend of the court") litigation program in FY 1989 by participating in five amicus cases. The principal mission of Legal Counsel staff in amicus cases is to assist the courts in resolving difficult or novel questions arising under the Commodity Exchange Act or Commission regulations and precedent, with an eye to making significant contributions to the development of consistent and accurate legal precedent.

Legal Counsel also conducted administrative litigation in FY 1989. Such litigation involves Commission personnel as well as the ethical standards of attorneys and accountants who appear or practice before the Commission. Personnel matters generally involve allegations by employees or former employees that they were denied equal employment opportunity or were subject to an unfair labor practice. In FY 1989, Legal Counsel handled four such matters. In contrast, Part 14 proceedings determine whether, based on prior conduct, particular attorneys or accountants should be denied the privilege of appearing or practicing before the Commission. In FY 1989, Legal Counsel handled one Part 14 matter at the litigation stage.

Opinions. The Legal Counsel staff manages the Commission's appellate docket by drafting opinions and orders of the Commission in appeals from the decisions of Administrative Law Judges and Judgment Officers in reparations and enforcement cases. Legal Counsel's Opinions Section also drafts opinions in appeals from disciplinary, membership, and registration actions taken by the exchanges and the National Futures Association ("NFA"). The Opinions Section also drafts opinions in appeals from disciplinary, access denial or other adverse actions by commodity exchanges. The staff works closely with the Commissioners and their legal assistants to develop substantive policies and efficient procedures for handling the Commission's large appellate administrative caseload.

In 1989, the opinions staff received 119 appeals, an overall reduction of thirty-five percent from the number filed in FY 1988. Because the number of matters completed was also below the anticipated level, however, the number of cases pending on the Commission's docket continued to grow. Reduction in case output is attributable to two primary factors: 1) an increase in cases raising complex factual issues or legal issues of first impression and 2) an increase in the time devoted by Opinions Section staff to duties that were not directly related to case production (e.g., rulemaking related to the opinions process).

Legal Advisor. Legal Counsel is the chief legal advisor to the Commission. In this role, Legal Counsel participates in the formulation of the Commission's regulatory policy, preparing advisory memoranda to the Commission on legal issues relating to regulatory initiatives, legislative proposals, and statutory interpretations. Legal Counsel is routinely available to the Commission and its operating divisions for legal consultation and advice.

The Legal Counsel staff also reviews documents prepared for the Commission by other divisions to ensure consistency with statutory requirements, Commission precedent and policy, and legal developments. In addition, the staff assists individual Commissioners and program managers in the development of the Commission's regulatory programs. The staff answers public inquiries concerning the Commission's statutory responsibilities and provides legal opinions to federal and state agencies with related regulatory interests. It also publishes formal interpretations involving questions arising under the Commodity Exchange Act that are of interest to a broad sector of the futures industry.

Legal Counsel provides support to the Commission's enforcement program by performing legal analyses and drafting background memoranda concerning enforcement actions. In FY 1989 Legal Counsel reviewed 99 proposed enforcement actions. A number of these cases involved complicated issues of law and fact that were analyzed under demanding time constraints.

Applications for contract market designation and proposed contract market rule changes are also reviewed by Legal Counsel. The Legal Counsel analyzed 163 of these matters in FY 1989.

Proposed Commission regulatory initiatives are also reviewed by the Legal Counsel staff. In addition, the staff often assumes primary responsibility for drafting proposed Commission rules. For example, during FY 1989, the staff drafted amendments to the Commission's Code of Conduct; wrote rules to govern the Commission's indemnification policy for employees that are sued for actions taken within the scope of their employment; and wrote the Commission's Statutory Interpretation Concerning Certain Hybrid Instruments, 54 F.R. 1128 (Jan. 11, 1989). In addition, Legal Counsel assisted in the implementation of the Inspector General Amendments Act of 1988 and continued to draft comprehensive rules to govern the Commission's review of decisions by registered futures associations. Legal Counsel also participated in the Commission's ongoing examination of hybrid instruments, swap transactions and related instruments. In this regard, Legal Counsel assisted the Commission in its promulgation of a Proposed Rule for the regulation of hybrids and assisted the Commission in its review of the public comments submitted in response both to that notice and the Statutory Interpretation on hybrids noted above.

In the legislative area, the Legal Counsel staff has devoted a substantial amount of time to the Commission's oversight of the futures markets. Legal Counsel reviewed various reports analyzing the current state of the futures and securities markets and assisted the Commission in formulating its position on specific proposals for reform. In addition, Legal Counsel addressed legislative proposals and congressional inquiries precipitated by the volatile market events of October 1987, the disclosure of civil and criminal investigations of trading practices on commodity futures exchanges, and the July 1989 emergency action taken by the CBOT in the soybean futures contract.

In this regard and as part of the reauthorization process, Legal Counsel's legislative work involved reviewing the Commodity Exchange Act for possible amendment. As part of this effort in FY 1989, Legal Counsel reviewed both the Act and its history as well as court and industry interpretations of the Act to assess the need, if any, for amendment. In FY 1989, Legal Counsel assisted the Commission in formulating several specific legislative proposals including, among others, recommendations for nationwide service of process in private rights of action under Section 22 of the Act, for registration of floor traders and for amendment of Section 6(d) to delete the requirement that the Commission consider a respondent's net worth before assessing a monetary penalty as a sanction for violation of the Act. Legal Counsel also assisted the Commission in its analysis of legislative proposals offered by members of Congress and the public. At the end of FY 1989, the House passed H.R. 2869, incorporating the Commission's proposals and other amendments to the Act designed to enhance the regulation of the futures markets, as the Senate Agriculture Committee was drafting similar legislation.

Legal Counsel also continued to expend significant staff resources on international matters. In this regard, Legal Counsel assisted in the Commission's review of requests for foreign exchanges that sought to engage in the offer and sale of foreign futures and options contracts in the United States and devoted resources to the Commission's effort to negotiate information sharing arrangements with foreign nations.

Finally, in discharging its duty as the Commission's legal advisor, Legal Counsel furnished advice on topics as diverse as rules or actions of the National Futures Association, Commission rules, ethics questions, Commission acquisition and contractual requirements, and personnel matters. The staff also helped to assure the Commission's compliance with the Rehabilitation Act, the Privacy Act, the Federal Advisory Committee Act, the Freedom of Information Act, the Budget and Accounting Procedures Act, the Government in the Sunshine Act, the Paperwork Reduction Act and the Regulatory Flexibility Act.

Planned Activities (FY 1990)

To a large extent, Legal Counsel's litigation caseload is a function of the Commission's enforcement activity and its reparations docket. Based on the Division of Enforcement's planned activities, and the current reparations docket, Legal Counsel anticipates that enforcement and particularly reparations litigation may increase in FY 1990. The staff also anticipates some increase in litigation stemming from Commission review of decisions of the National Futures Association and individual commodity exchanges.

With the exception of amicus cases, Legal Counsel's litigation is a mandatory program, since Legal Counsel must defend the agency when it is sued. Moreover, even Legal Counsel's amicus participation is in part obligatory since the Commission is often called upon to clarify important aspects of commodities law, either to forestall future litigation or at the direct request of a reviewing court.

Based upon recent trends in the number of reparations and enforcement cases received on appeal, the Opinions Section expects that its FY 1990 caseload will exceed the level experienced in FY 1989. Cases involving the review of exchange and registered futures association proceedings are expected to continue to increase.

Predicting Legal Counsel's advisory workload is more difficult because such work is largely dependent upon a variety of external factors, including the activity of other Commission programs; requests for legal analysis from the Commission, individual Commissioners, and other divisions; inquiries from federal and state officials; legal issues encountered by the National Futures Association; proposed Congressional legislation that requires Commission comment; and requests for legal interpretations from commodities professionals and members of the public. Nevertheless, the following issues assure that the legal advisory staff workload will remain high in FY 1990.

First, the volatility of the financial markets has given rise to a variety of legislative and regulatory proposals. In FY 1990, Legal Counsel will continue to analyze these proposals to assist the Commission in its policy development. Second, the increased focus on futures trading precipitated by investigations of exchange floor trading practices has resulted in a variety of legislative and regulatory proposals that Legal Counsel will continue to study. Third, Legal Counsel will continue to assist the Commission in its ongoing examination of the expanding market in off-exchange hybrid instruments and related instruments. Fourth, the staff anticipates that the Commission's Code of Conduct will require significant amendment in FY 1990 in light of the recently issued Executive Order No. 12674 which governs the ethical conduct of federal employees. Finally, Legal Counsel will continue to assist the Commission in overseeing the growing internationalization of the futures markets.

As noted above, in FY 1989 the Commodity Exchange Act was before Congress for reauthorization. Since Congress did not complete its work on reauthorization in FY 1989, the Act will again be before Congress for reauthorization in FY 1990. In these circumstances, Legal Counsel's obligation to critique proposed legislative reforms, to draft proposed amendments and to coordinate the Commission's legislative agenda before Congress will continue in FY 1990. Legal Counsel also anticipates that it will continue to provide support to the Commission as it addresses congressional inquiries from its oversight committees as well as individual members of Congress. Finally, Legal Counsel expects to continue its cooperative efforts with staff at other federal agencies, including the Securities and Exchange Commission, the Internal Revenue Service, the Department of Agriculture, the Federal Reserve, the Department of Treasury, the Office of the Comptroller of the Currency and the State Department.

In FY 1990, Legal Counsel anticipates that it will continue to consider a variety of international matters. Illustratively, Legal Counsel will continue to spend significant staff resources reviewing the implementation of the foreign futures and option rules. In addition, Legal Counsel expects that the Commission will continue to pursue information sharing agreements with foreign governments and that Legal Counsel will expend resources in implementing this goal.

Legal Counsel anticipates that its staffing level will be adequate to produce a high-quality legal product in the broad range of litigation, advisory, and opinions activity anticipated in FY 1990.

Impact of the Current Level (FY 1991)

In recent years, Legal Counsel has successfully met its goal of providing expert legal advice and representation to the Commission, its operating divisions and the public despite incurring significant strain upon its staff. Legal Counsel's FY 1991 request is designed to ensure that the staff will continue to meet its obligations to the Commission, its operating division and the public.

Although it is difficult to predict Legal Counsel activity more than a year in advance, certain reliable assessments concerning FY 1991 can be made. As futures and options trading continues to expand, and as public participation in such trading continues to grow, Legal Counsel can safely project that its litigation and opinions caseloads will remain high. In addition, given the increasing internationalization and proliferation of financial and futures markets and instruments, Legal Counsel anticipates that its regulatory agenda will remain filled with novel questions of law (i.e., issues of international law, computerized trading, hybrids) that will demand significant staff resources. Legal Counsel's work on legislative initiatives is also likely to continue into FY 1991.

Justification of Request (FY 1991)

The requested increase of two full-time equivalent staff years will allow Legal Counsel to continue to provide expert legal advice and representation to the Commission, its operating divisions, and the public. Specifically, Legal Counsel anticipates placing one position in its Opinions Section and one in its advisory staff.

The addition of one position to Legal Counsel's Opinions Section will enable that section to assist the Commission in ensuring timely disposition of its adjudicatory function. Absent this request, the length of time from the filing of a case to the Commission's issuance of a decision is likely to increase.

The other additional staff position will give Legal Counsel the resources to handle the increase in work generated by the expected increase in the level of Commission enforcement activity. This increase will be felt initially in the review stage as Legal Counsel discharges its obligation to review proposed enforcement actions; later it can be expected to affect Legal Counsel's appellate litigation caseload. Any attempt by Legal Counsel to meet these anticipated demands at current staff levels would result in undue strain upon existing personnel.

APPENDIX A

REPORT ON OBLIGATIONS FOR INFORMATION TECHNOLOGY SYSTEMS

A11-43A

REPORT ON OBLIGATIONS FOR INFORMATION TECHNOLOGY SYSTEMS
SUMMARY OF OBLIGATIONS FY 1989 - FY 1991

		FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
1.	CAPITAL INVESTMENT ($000)			
	A. Purchase of Equipment	1,047	465	1,740
	B. Purchase of Software and Other Equipment	65	83	55
	C. Site or Facility	53	48	78
2.	PERSONNEL ($000)			
	A. Compensation, Benefits and Travel	1,295	1,548	1,735
	B. Work-Years	(28)	(28)	(33)
3.	EQUIPMENT, RENTAL, SPACE AND OTHER OPERATIONAL COST ($000)			
	A. Lease of Information	0	0	0
	B. Space	273	282	293
	C. Supplies and Other	398	447	456
4.	COMMERCIAL SERVICES ($000)			
	A. ADP Time	161	223	238
	B. Leased Services	75	120	120
	C. Operations and Maintenance	228	302	363
	D. Systems Analysis and Programming	261	427	427
	E. System Design and Engineering	0	0	0
	F. Studies and Other	20	25	30
5.	INTERAGENCY SERVICES ($000)			
	A. Payments	88	95	104
		3,964	4,065	5,639

ESTIMATE OF OBLIGATIONS FOR FY 1990

1. CAPITAL INVESTMENT ($000)		
A. PURCHASE OF EQUIPMENT		$ 465
-- Additional Personal Computers to Increase Efficiency of Professional Staff (75 Units)	($300,000)	
-- Additional Network File Servers to Support Expanding PC Population (4)	($100,000)	
-- Replacement Terminals, Modems, Switches, Laser Printers, etc	($ 65,000)	
B. PURCHASE OF SOFTWARE		$ 83
-- Microcomputer Software Packages for Additional PC's and Expanded Software Requirements	($ 83,000)	
C. SITE OR FACILITY		$ 48
-- Network Cabling Required to Support Additional File Servers	($ 40,000)	
-- Specialized ADP/Network Furniture	($ 8,000)	
2. PERSONNEL ($000)		
A. COMPENSATION, BENEFITS AND TRAVEL		$ 1,548
B. WORK YEARS		(28)
3. EQUIPMENT RENTAL, SPACE AND OTHER OPERATIONAL COSTS ($000)		
A. LEASE OF INFORMATION TECHNOLOGY EQUIPMENT		$ 0
B. SPACE		$ 282
C. SUPPLIES AND OTHER		$ 447
-- Supplies	($115,000)	
-- IBM MVS/XA Operating System	($166,000)	
-- Datacomm DBMS	($ 52,000)	
-- Top Secret Security Package	($ 3,000)	
-- Statistical Software	($ 24,000)	
-- Tape Management System	($ 4,000)	

	-- FDR, ABR, Compaktor	($ 5,000)	
	-- JARS Accounting System	($ 3,000)	
	-- Syncsort	($ 4,000)	
	-- FFS Financial Management System	($ 49,000)	
	-- Banyan Network Operating System	($ 22,000)	
4.	COMMERCIAL SERVICES ($000)		
A.	ADP TIME		$ 223
	-- RCC Market Research	($ 5,000)	
	-- LEXIS/WESTLAW/JURIS Research	($195,000)	
	-- Library Services	($ 23,000)	
B.	LEASED SERVICES		$ 120
	-- Communication Lines for Mainframe and Expanded Microcomputer Network	($120,000)	
C.	OPERATIONS AND MAINTENANCE		$ 302
	-- Computer Output Microfiche Services	($ 4,000)	
	-- Maintenance IBM 4381 Processor	($ 10,000)	
	-- Maintenance of Tape Drives and Printer	($ 85,000)	
	-- Maintenance Disk Drives	($ 25,000)	
	-- Maintenance Front End Processor	($ 8,000)	
	-- Maintenance Terminals and Remote Controllers	($ 39,000)	
	-- Maintenance Remote Site Printers	($ 43,000)	
	-- Maintenance Microcomputer Network File Servers	($ 41,000)	
	-- Maintenance Microcomputers	($ 35,000)	
	-- Maintenance Chicago Data Center A/C	($ 8,000)	
	-- Maintenance Washington Operations Center A/C	($ 4,000)	
D.	SYSTEMS ANALYSIS AND PROGRAMMING		$ 427
	-- Applications Programming Support	($280,000)	
	-- Systems Programming Support	($120,000)	
	-- Technical Support for Financial Management System (Per Contract)	($ 27,000)	
E.	SYSTEM DESIGN AND ENGINEERING		$ 0
F.	STUDIES AND OTHER		$ 25

-- Commercial Training	($ 25,000)	
5. INTERAGENCY SERVICES ($000)		
A. PAYMENTS		$ 95
-- Personnel/Payroll System (Outside Vendor)	($ 95,000)	
TOTAL		$ 4,065

ESTIMATE OF OBLIGATIONS FOR FY 1991

1. CAPITAL INVESTMENT ($000)		
A. PURCHASE OF EQUIPMENT		$ 1,740
-- New Mainframe Computer System (Per Long Range ADP Plan)	($1,430,000)	
-- Additional Personal Computers to Increase Efficiency of Professional Staff (40 Units)	($285,000)	
-- Replacement Terminals, Modems, Switches, etc.	($ 25,000)	
B. PURCHASE OF SOFTWARE		$ 55
-- Microcomputer Software Packages for Additional PC's and Expanded Software Requirements	($ 55,000)	
C. SITE OR FACILITY		$ 78
-- Modifications to Data Center to Support New Computer System	($ 70,000)	
-- Specialized ADP/Network Furniture	($ 8,000)	
2. PERSONNEL ($000)		
A. COMPENSATION, BENEFITS AND TRAVEL		$ 1,735
B. WORK YEARS		(33)
3. EQUIPMENT RENTAL, SPACE AND OTHER OPERATIONAL COSTS ($000)		
A. LEASE OF INFORMATION TECHNOLOGY EQUIPMENT		$ 0
B. SPACE		$ 293
C. SUPPLIES AND OTHER		$ 456
-- Supplies	($119,000)	
-- IBM MVS/XA Operating System	($166,000)	
-- Datacomm DBMS	($ 52,000)	
-- Top Secret Security Package	($ 3,000)	
-- Statistical Software	($ 24,000)	
-- Tape Management System	($ 4,000)	
-- FDR, ABR, Compaktor	($ 5,000)	
-- JARS Accounting System	($ 3,000)	

	-- Syncsort	($ 4,000)	
	-- FFS Financial Management System	($ 49,000)	
	-- Banyan Network Operating System	($ 27,000)	
4.	COMMERCIAL SERVICES ($000)		
A.	ADP TIME		$ 238
	-- RCC Market Research	($ 5,000)	
	-- LEXIS/WESTLAW/JURIS Research	($210,000)	
	-- Library Services	($ 23,000)	
B.	LEASED SERVICES		$ 120
	-- Communication Lines for Mainframe and Expanded Microcomputer Network	($120,000)	
C.	OPERATIONS AND MAINTENANCE		$ 363
	-- Computer Output Microfiche Services	($ 4,000)	
	-- Maintenance New Computer System	($ 56,000)	
	-- Maintenance of Tape Drives and Printer	($ 85,000)	
	-- Maintenance Disk Drives	($ 25,000)	
	-- Maintenance Front End Processor	($ 8,000)	
	-- Maintenance Terminals and Remote Controllers	($ 39,000)	
	-- Maintenance Remote Site Printers	($ 43,500)	
	-- Maintenance Microcomputer Network File Servers	($ 49,500)	
	-- Maintenance Microcomputers	($ 40,000)	
	-- Maintenance Chicago Data Center A/C	($ 8,500)	
	-- Maintenance Washington Operations Center A/C	($ 4,000)	
D.	SYSTEMS ANALYSIS AND PROGRAMMING		$ 427
	-- Applications Programming Support	($280,000)	
	-- Systems Programming Support	($120,000)	
	-- Technical Support for Financial Management System (Per Contract)	($ 27,000)	
E.	SYSTEM DESIGN AND ENGINEERING		$ 0
F.	STUDIES AND OTHER		$ 30
	-- Commercial Training	($ 30,000)	

5. INTERAGENCY SERVICES ($000)

A. PAYMENTS		$ 104
-- Personnel/Payroll System (Outside Vendor)	($104,000)	
TOTAL		$ 5,639

APPENDIX B

PREFORMANCE STATISTICS

PERFORMANCE STATISTICS

ENFORCEMENT

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
INVESTIGATIONS			
Pending Beginning of Fiscal Year	109	130	136
New Investigations Opened	89	70	72
Investigations Closed	68	64	66
Pending End of Fiscal Year	130	136	142
LITIGATION			
Pending Beginning of Fiscal Year	119	113	114
New Cases Opened	50	54	56
Cases Completed	56	53	55
Pending End of Fiscal Year	113	114	115

PERFORMANCE STATISTICS
MARKET ANALYSIS

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
New Futures Contracts -- Completed Reviews	14	14	14
Economic Analyses of Futures Rule Changes Completed	89	91	93
New Option Contracts-- Completed Reviews	3	4	5
Economic Analyses of Option Rule Changes Completed	26	27	28

PERFORMANCE STATISTICS
MARKET SURVEILLANCE

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Weekly Surveillance Sheets Prepared	2,512	2,700	2,900
Special Market Surveillance Reports	60	75	85
Reports from Traders and Brokers Processed	732,834	780,000	820,000
FCM Audits	185	190	200
Exchange Reviews for Speculative Limits	2	2	2
Information Letters Sent	8,318	9,000	9,500
Compliance Letters:			
Reporting Requirement	3,248	3,400	3,600
Speculative Limit	77	110	110
Permanent Records Tables Prepared	9,378	9,700	10,000
Reports Published	1,493	1,500	1,500

PERFORMANCE STATISTICS
CONTRACT MARKETS AND REGISTERED FUTURES ASSOCIATIONS

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Review of Proposed Exchange Rules			
1.41(b)--terms and conditions	790	820	825
1.41(c)--all other rules	258	460	475
Trade Practice Investigations	53	70	120
Completed Reviews of Contract Market Designations--Futures and Options	17	18	19
Approval of Inter-Market Affiliations	0	1	1
Rule Enforcement Reviews	4	5	7
Exchange and NFA Disciplinary Actions Received	631	650	700
Enforcement Referrals:			
To Self-Regulatory Organizations	25	30	45
To Division of Enforcement	9	10	18

PERFORMANCE STATISTICS
REGULATORY DEVELOPMENT AND REGISTRATION

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Regulatory Development			
General Correspondence	101	100	120
Exemption Requests	103	110	120
No-Action Requests	48	55	65
Interpretations	61	70	75
Total	313	335	380
Registration			
Licenses Granted to Associated Persons of Leverage Transaction Merchants	15*	0*	0*
Fitness Reviews of Floor Brokers and Leverage Transaction Merchants' Associated Persons**	159	160	160
Notices of Intent to Deny Registration and Referrals to Division of Enforcement for Commission Action	23	24	24
Review of Requests to Withdraw Firm Registrations	968	1,000	1,000
Civil Penalty Collection ('000)			
New Penalties Due	$6,020	$2,500	$3,000
Collected	5,658	1,500	2,100
Written-Off	202	1,500	1,500
Total Penalties Outstanding at End of FY	$8,799	$8,300	$7,700

* The Commission authorized the National Futures Association to perform this function on May 15, 1989 under Commission oversight.

** The Commission authorized the National Futures Association to perform the function of reviewing the fitness of leverage transaction merchants and associated persons of leverage transaction merchants during FY 1990, effective January 1, 1990. If Congress approves the Commission's recommendation to require registration of floor traders, the subprogram staff would conduct fitness reviews of floor traders as it now does for floor brokers.

PERFORMANCE STATISTICS
SALES PRACTICE AND MANAGED FUNDS

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Full Scope and Follow-Up Rule Enforcement Reviews of Self-Regulatory Organization Sales Practice Audit and Surveillance Programs	3	4	4
Audits of Leverage Transaction Merchants	0	1	0
Direct Oversight Audits of Futures Commission Merchants, Introducing Brokers, Commodity Pool Operators, and Commodity Trading Advisors	18	10	15
Commodity Pool Operator and Commodity Trading Advisor Disclosure Documents:			
Reviewed	3,440	3,300	3,500
Deficiency Letters Issued	1,203	1,200	1,300
Responses to Commodity Pool Operator and Commodity Trading Advisor Written Requests for Exemption and Interpretation	111	130	135

PERFORMANCE STATISTICS
FINANCIAL AUDIT AND REVIEW

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
SRO Financial Rule Enforcement Reviews	2	4	6
In-field Audits:			
Futures Commission Merchants	37	45	45
Commodity Pools	18	25	25
Leverage Transaction Merchants*	3	1	0
Other Registrants	18	20	20
Financial Investigative Reviews	10	10	10
Warning and Noncompliance Letters Issued	153	160	175
Financial Reports Reviewed	4,108	4,000	4,000
Interpretations, Exemptions No-Actions and Relief Letters Issued	67	60	65
Notices of Violations Received and Investigated	73	160	170

* The Commission has authorized the National Futures Association to perform direct audits of leverage transaction merchants starting FY 1990.

PERFORMANCE STATISTICS

PROCEEDINGS

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
REPARATIONS CASES			
Complaints Section			
Complaints Pending Beginning of Fiscal Year	106	56	56
Complaints Filed	385	400	450
Complaints Dismissed	50	35	35
Complaints Forwarded for All Types of Proceedings	385	365	415
Complaints Pending End of Fiscal Year	56	56	56
Hearings Section			
Cases Pending Beginning of Fiscal Year	307	292	292
Cases Received for All Types of Proceedings*	413	450	450
Cases Dismissed for Cause	18	30	30
Cases Settled	167	150	150
Cases Disposed of by Default	30	20	20
Cases Disposed of by Initial Decision	213	250	250
Total Dispositions	428	450	450
Cases Pending at End of Fiscal Year	292	292	292

* Includes Remands and Reconsiderations.

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
ENFORCEMENT CASES			
Hearings Section			
Cases Pending Beginning of Fiscal Year	40	40	40
Cases Received for Adjudication*	38	34	34
Cases Settled	8	10	10
Decisions Issued	30	24	24
Total Dispositions	38	34	34
Cases Pending at End of Fiscal Year	40	40	40
REPARATIONS INQUIRIES			
Telephone Inquiries	15,000	15,000	15,000
Walk-In Inquiries	800	800	800
Written Inquiries	1,100	1,100	1,100
Brochures Sent	2,500	2,500	2,500

* Includes Remands and Reconsiderations.

PERFORMANCE STATISTICS

LEGAL COUNSEL

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Appellate Litigation			
Reparations	13	26	28
Enforcement Petitions	5	10	10
Enforcement Appeals	5	12	12
Rules/Regulatory Actions	1	2	2
Amicus	5	6	6
Other	3	5	5
Total Appellate	32	61	63
District Court Litigation			
Enforcement	7	8	8
Rules/Regulatory Actions	0	2	2
Amicus	0	2	2
Private Subpoenas	27	30	32
Bankruptcy	21	20	20
Other	4	4	4
Total District Court	59	66	68
Administrative Litigation			
Personnel	4	7	8
FOIA	22	22	24
Other	1	5	5
Total Administrative	27	34	37
GRAND TOTAL	118	161	168

PERFORMANCE STATISTICS

LEGAL COUNSEL -- OPINIONS

	FY 1989 ACTUAL	FY 1990 ESTIMATE	FY 1991 REQUEST
Matters Pending at Beginning of Fiscal Year	109	149	179
Matters Received During Fiscal Year	119	150	160
Matters Completed During Fiscal Year	79	120	150
Matters Pending at End of Fiscal Year	149	179	189

APPENDIX C

SUMMARY OF FUTURES AND OPTIONS TRADING IN FY 1989

FUTURES--AVERAGE MONTHEND OPEN INTEREST, ESTIMATED NUMBER OF CONTRACTS TRADED AND
NUMBER OF CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT BY
MAJOR GROUPS, ALL MARKETS COMBINED

FISCAL YEAR	TOTAL	GRAIN	OILSEEDS/ PRODUCTS	LIVESTOCK/ PRODUCTS	OTHER AGRICULTURALS	ENERGY/WOOD PRODUCTS	METALS	FINANCIAL INSTRUMENTS	CURRENCIES
AVERAGE MONTHEND OPEN INTEREST (IN CONTRACTS)									
1983	1,603,818	264,859	215,929	119,160	159,523	57,916	335,174	332,588	118,669
1984	1,779,206	291,083	223,056	104,086	172,015	75,613	360,888	371,330	180,935
1985	1,758,371	212,157	173,058	100,667	159,742	97,810	350,531	523,301	141,105
1986	1,973,043	200,054	183,495	107,708	171,371	145,815	328,101	665,617	170,882
1987	2,370,625	197,679	216,076	137,866	157,371	277,783	362,709	840,018	181,123
1988	2,827,974	280,761	288,187	145,246	242,857	304,131	303,305	1,059,898	203,589
1989	3,170,803	308,792	254,931	143,014	262,714	344,208	322,559	1,336,012	198,573
NUMBER OF CONTRACTS TRADED									
1983	136,077,049	17,793,846	19,823,188	11,062,975	6,323,575	3,204,209	26,316,268	40,154,894	11,398,094
1984	148,822,234	15,889,408	23,488,506	8,429,245	5,958,457	4,945,907	22,446,535	51,003,284	16,660,892
1985	152,589,653	10,726,379	14,883,445	7,925,991	5,140,901	7,025,002	18,383,469	72,127,016	16,377,450
1986	183,098,076	10,315,267	13,798,988	8,571.157	6,699.770	11,530,975	16,233,964	96,886,878	19,061,077
1987	213,546,854	10,944,716	14,151,700	8,755,283	5,719,074	20,306,103	19,426,457	114,336,601	19,906,920
1988	241,760,755	15,908,256	22,486,694	9,561,778	9,763,731	26,271,365	18,937,976	117,646,562	21,184,393
1989	267,658,390	15,920,321	21,104,497	8,185,955	10,749,030	31,343,764	17,941,194	136,729,387	25,684,242
NUMBER OF CONTRACTS SETTLED BY DELIVERY/CASH SETTLEMENT									
1983	806,308	73,394	188,454	8,740	23,086	24,848	305,655	116,066	66,065
1984	1,208,102	109,644	438,441	10,265	21,437	39,858	284,614	161,284	142,559
1985	1,170,428	133,794	192,502	15,068	27,641	56,898	242,871	341,328	160,326
1986	1,246,836	67,983	174,492	8,745	30,761	43.139	234,069	447,756	239,891
1987	1,318,906	64,986	120,763	11,106	26,815	47,417	235,795	518,365	293,659
1988	1,535,817	109,261	155,727	17,299	35,494	34,245	222,014	567,347	394,430
1989	1,742,040	57,424	176,140	12,171	42,251	38,355	180,708	854,536	380,455

CONTRACTS SETTLED BY DELIVERY FOR GRAIN AND OILSEEDS/PRODUCTS FOR FISCAL YEARS 1987 AND 1988 HAVE BEEN REVISED.

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST, 12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

CHICAGO BOARD OF TRADE (CBT)	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
WHEAT	5,000 BU.	45,246	63,625	3,026,759	3,458,621	21,788	14,921
CORN	5,000 BU.	178,035	182,767	10,069,852	9,663,059	52,998	16,508
OATS	5,000 BU.	7,467	9,491	346,438	367,650	3,568	4,760
SOYBEANS	5,000 BU.	124,293	101,160	11,810,978	10,619,238	50,391	22,848
OIL, SOYBEAN	60,000 LBS.	84,568	74,887	4,877,711	4,361,463	98,878	139,311
MEAL, SOYBEAN	100 TONS	69,984	65,529	5,014,894	4,920,586	2,602	8,947
US TREASURY BONDS	$100,000	363,803	346,887	69,246,337	72,639,796	62,671	64,451
US TREASURY NOTES (5 YR)	$100,000	10,150	40,400	262,838	1,506,994	1,510	43,910
US TREASURY NOTES (6.5-10 YR)	$100,000	81,326	80,893	5,227,872	6,106,853	30,311	45,471
GNMA (MORTGAGES) CDR	$100,000	1,132	0	488	0	462	0
STOCK INDEX, MAXI MM 1/	INDEX X $250	3,950	4,693	1,365,473	1,052,409	32,069	41,881
STOCK INDEX, MVI 1/ 2/	INDEX X $100	---	0	---	912	---	0
MUNICIPAL BONDS 1/	INDEX X $1,000	15,394	16,753	1,430,431	1,026,942	9,379	8,499
STOCK INDEX, INSTITUT.	INDEX X $500	0	0	2	0	10	0
30-DAY INTEREST RATES 1/ 2/	$5,000,000	---	2,978	---	69,564	---	5,080
GNMA (MORTGAGES) 9% 1/ 3/	$100.00	---	7	---	122	---	10
GNMA (MORTGAGES) 9 1/2 1/ 3/	$100.00	---	1,100	---	19,132	---	1,898
STOCK INDEX,CBOE 250 1/ 4/	INDEX X 500	---	269	---	69,785	---	908
CORPORATE BOND INDEX	$1,000,0000	179	0	10,640	0	377	0
SILVER	1,000 TR. OZ.	11,556	10,106	443,678	297,703	10,035	10,704
SILVER	5,000 TR. OZ.	185	183	9,726	3,170	411	378
GOLD	1 KILOGRAM	1,347	527	114,470	38,318	2,119	365
GOLD	100 TR. OZ.	508	1,328	64,360	105,389	1,437	2,093
TOTAL CBT		999,123	1,003,583	113,322,947	116,327,706	381,016	432,943

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST, 12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
MID AMERICA COMMODITY EXCHANGE (MCE)							
WHEAT	1,000 BU.	5,584	8,455	272,339	334,080	4,194	1,638
CORN	1,000 BU.	9,131	6,791	424,131	346,067	6,098	5,016
OATS	1,000 BU.	296	615	10,403	15,017	266	1,020
SOYBEANS	1,000 BU.	8,851	12,824	775,523	1,195,910	3,644	4,735
MEAL, SOYBEAN	20 TONS	491	531	7,588	7,300	212	299
US TREASURY BONDS	$50,000	5,508	6,396	1,363,500	1,273,141	1,162	1,994
US TREASURY BILLS 1/	$500,000	340	77	30,907	7,948	14	6
US TREASURY NOTES	$100,000	77	29	3,628	683	10	40
HOGS, LIVE	15,000 LBS.	781	687	35,895	31,108	55	59
CATTLE, LIVE	20,000 LBS.	681	571	52,633	30,222	36	38
SILVER, NY DEL	1,000 TR. OZ.	389	1,165	12,469	11,238	142	339
GOLD, NY DEL	33.2 TR. OZ.	272	166	13,665	11,056	90	45
PLATINUM	25 TR. OZ.	54	35	2,886	2,121	11	0
DOLLARS, CANADIAN	50,000	99	70	7,698	7,753	0	0
FRANC, SWISS	62,500	634	319	85,714	61,775	4	6
MARK, DEUTSCHE	62,500	368	353	53,896	50,424	4	3
POUND STERLING	12,500	283	237	26,033	22,280	10	22
YEN, JAPANESE	6,250,000	296	327	44,718	54,897	10	0
TOTAL MCE		34,135	39,648	3,223,626	3,463,020	15,962	15,260
KANSAS CITY BD OF TRADE (KCBT)							
WHEAT	5,000 BU.	24,710	26,310	1,285,016	1,292,478	9,726	6,893
GRAIN SORGHUMS 5/	5,000 BU.	---	560	---	6,056	---	0
STOCK INDEX, VLA 1/	INDEX X $500	2,216	1,454	114,696	44,625	2,162	952
STOCK INDEX, MVL 1/	INDEX X $100	141	134	17,522	8,577	103	92
TOTAL KCBT		27,067	28,458	1,417,234	1,351,736	11,991	7,937
MINNEAPOLIS GRAIN EXCHANGE (MGE)							
WHEAT	5,000 BU.	7,898	7,710	414,587	390,206	6,330	4,347
WHEAT, WHITE	5,000 BU.	46	19	493	71	85	0
OATS 6/	5,000 BU.	---	145	---	1,957	---	54
CORN SYRUP, HIGH FRUCTOSE	48,000 LB.	5	1	74	1	8	0
TOTAL MGE		7,949	7,875	415,154	392,235	6,423	4,401

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST, 12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
CHICAGO MERCANTILE EXCHANGE (CME) AND INTERNATIONAL MONETARY MARKET (IMM)							
HOGS, LIVE	30,000 LBS.	27,644	29,373	1,949,498	1,826,686	311	342
PORK BELLIES	38,000 LBS.	13,344	19,402	1,096,285	1,232,218	2,673	2,547
CATTLE, LIVE	40,000 IBS.	84,100	79,438	5,642,313	4,569,216	1,013	1,560
CATTLE, FEEDER	42,000 LBS.	18,696	13,543	785,154	496,505	13,211	7,617
LUMBER	130,000 BD FT	5,999	7,319	399,499	297,000	72	82
US TREASURY BILLS	$1,000,000	22,897	24,234	1,593,106	1,433,495	7,466	8,998
DOLLARS, AUSTRALIAN	100,000	2,934	2,449	66,861	112,785	11,909	6,832
DOLLARS, CANADIAN	100,000	24,385	25,475	1,147,215	1,439,482	29,990	39,019
FRANC, FRENCH	250,000	235	192	2,842	4,028	739	189
FRANC, SWISS	125,000	29,984	34,348	5,248,670	6,007,693	63,365	51,708
MARK, DEUTSCHE	125,000	46,702	57,603	5,464,078	7,624,262	114,166	124,700
POUND STERLING	25,000	39,450	0	2,030,225	0	70,626	0
POUND STERLING (NEW)	25,000	7,841	23,108	727,702	2,478,495	8,735	43,611
YEN, JAPANESE	12,500,000	49,954	53,780	6,277,721	7,819,788	93,733	114,103
EURODOLLARS 1/	$1,000,000	401,044	646,754	21,158,066	37,665,062	275,491	457,535
STOCK INDEX, S&P 500 1/	INDEX X $500	120,743	130,472	12,549,807	10,549,275	121,116	127,928
EURO-MARK RATE DIFF 1/ 7/	$1,000,000	---	380	---	9,343	---	198
EURO-POUND RATE DIFF1/ 7/	$1,000,000	---	328	---	7,467	---	128
EURO-YEN RATE DIFF 1/ 7/	$1,000,000	---	470	---	6,247	---	166
GOLD, LONDON DEL	100 TR. OZ.	407	0	21,338	0	523	0
GOLD, NY DEL	5,000 TR. OZ.	1,142	0	839	0	2,047	0
TOTAL CME/IMM		897,501	1,148,668	66,161,219	83,579,047	817,186	987,271
CHICAGO RICE & COTTON EXCHANGE (CRCE)							
RICE, ROUGH	200,000 LBS.	2,348	2,304	58,238	45,059	4,208	2,267
TOTAL CRCE		2,348	2,304	58,238	45,059	4,208	2,267

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST,
12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY
FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
NEW YORK MERCANTILE EXCHANGE (NYME)							
OIL, HEATING NO. 2	42,000 GALLONS	64,565	67,993	4,864,873	5,265,943	10,884	9,856
OIL, CRUDE (SWEET)	1,000 BARRELS	187,792	213,182	18,079,425	21,432,325	11,259	15,012
PALLADIUM	100 TR. OZ.	6,630	7,416	150,906	203,347	2,607	2,673
PLATINUM	50 TR. OZ.	19,513	19,489	1,308,835	1,395,103	11,467	5,810
GASOLINE, UNLEADED	42,000 GALLONS	44,542	55,057	2,895,824	4,334,013	11,059	12,904
PROPANE GAS	42,000 GALLONS	1,217	657	31,645	14,483	916	501
TOTAL NYME		324,259	363,794	27,331,508	32,645,214	48,192	46,756
NEW YORK COTTON EXCHANGE & ASSO. (NYCE)							
COTTON NO. 2	50,000 LBS.	33,172	37,640	1,383,427	1,546,271	3,926	5,307
ORANGE JUICE	15,000 LBS.	11,641	7,890	353,655	302,328	4,094	4,319
PROPANE GAS	42,000 GALLONS	16	0	99	0	55	0
DOLLAR INDEX 1/	INDEX X $500	5,448	6,656	436,988	720,268	3,503	5,157
EUROPEAN CURRENCY UNIT	100,000	1,327	239	27,934	12,686	851	966
U.S. TREASURY NOTES (5 YR.)	$100,000	8,051	11,202	727,934	595,311	4,894	23,950
U.S. TREASURY NOTES (2 YR.) 8/	$200,000	---	3,202	---	106,783	---	6,737
TOTAL NYCE		59,655	66,829	2,930,037	3,283,647	17,323	46,436
COFFEE, SUGAR AND COCOA EXCHANGE (CSCE)							
COCOA	10 METRIC TONS	33,367	37,648	1,113,269	1,438,169	5,991	3,733
SUGAR NO. 11	112,000 LBS.	133,937	148,720	5,766,747	6,034,900	7,495	18,584
WHITE SUGAR	112,000 LBS.	355	0	1,631	0	0	0
SUGAR NO. 14	112,000 LBS.	7,564	7,942	81,680	97,251	3,243	4,530
COFFEE C	37,500 LBS.	22,816	22,873	1,063,248	1,330,110	10,737	5,778
INDEX, CPI-W 1/	INDEX X $1,000	1	0	0	0	0	0
INTL. MARKET INDEX 1/ 9/	INDEX X $250	---	31	---	382	---	0
TOTAL CSCE		198,040	217,214	8,026,575	8,900,812	27,466	32,625

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST, 12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
COMMODITY EXCHANGE INC. (CMX)							
SILVER	5,000 TR. OZ.	75,255	90,155	4,744,192	4,156,107	84,923	83,276
COPPER	25,000 LBS.	37,382	30,432	2,228,900	2,272,031	7,727	14,779
COPPER (HIGH GRADE)	25,000 LBS.	105	1,443	393	17,250	0	840
GOLD	100 TR. OZ.	148,275	159,979	9,818,082	9,427,517	98,205	59,337
ALUMINUM	40,000 LBS.	285	135	3,237	844	270	69
MOODY CORP. INDEX	INDEX X $500	204	0	11,482	0	0	0
TOTAL CMX		261,506	282,144	16,806,286	15,873,749	191,125	158,301
NEW YORK FUTURES EXCHANGE (NYFE)							
STOCK INDEX, NYSE CMP 1/	INDEX X $500	6,235	0	423,727	0	1,697	0
STOCK INDEX, NYSE CMP (NEW) 1/	INDEX X $500	6,085	6,918	1,429,787	1,624,292	8,334	5,262
CMDTY RSRCH BR. INDEX 1/	INDEX X $500	3,077	2,326	207,393	143,858	2,653	2,269
CMDTY RSRCH BR. INDEX 1/ 10/	INDEX X $500	---	2	---	580	---	0
INDEX, RUSSEL 2000	INDEX X $500	124	0	2,500	0	287	0
INDEX, RUSSEL 3000	INDEX X $500	446	0	3,504	0	815	0
US TREASURY BONDS 11/	$100,000	---	728	---	26,855	---	50
TOTAL NYFE		15,967	9,974	2,066,911	1,795,585	13,786	7,581

CONTRACT MARKET REVIEW/ESTIMATED AVERAGE OPEN INTEREST, 12-MONTH VOLUME OF TRADING AND DELIVERIES/CASH SETTLEMENT BY COMMODITY FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	CONTRACT UNIT	MONTHEND OPEN INTEREST (Contracts)		VOLUME OF TRADING (Contracts)		TOTAL CONTRACTS SETTLED BY DELIVERY OR CASH SETTLEMENT (Contracts)	
		1987-88	1988-89	1987-88	1988-89	1987-88	1988-89
PHILADELPHIA BOARD OF TRADE							
FRANC, SWISS	125,000	136	15	30	77	220	0
MARK, DEUTSCHE	125,000	247	0	739	0	745	0
POUND STERLING	25,000	0	0	82	0	0	0
YEN, JAPANESE	12,500,000	2	297	10	493	2	262
DOLLARS, CANADIAN	100,000	39	0	159	0	172	0
DOLLARS, AUSTRALIAN	100,000	0	0	0	10	0	0
TOTAL PBOT		424	312	1,020	580	1,139	262
TOTAL ALL MARKETS		2,827,974	3,170,803	241,760,755	267,658,390	1,535,817	1,742,040

Total contracts settled by delivery for grain on CBT, KCBT and MGE for Fiscal Year 1987-88 have been revised.

1/ Cash settlement.
2/ Trading began October 3, 1988.
3/ Trading began June 16, 1989.
4/ Trading began November 11, 1988.
5/ Trading began May 5, 1989.
6/ Trading began October 18, 1988.
7/ Trading began July 6, 1989.
8/ Trading began February 22, 1989.
9/ Trading began May 12, 1989.
10/ Trading began July 25, 1989.
11/ Trading began August 4, 1989.

OPTIONS--AVERAGE MONTHEND OPEN INTEREST AND ESTIMATED NUMBER OF CONTRACTS TRADED BY MAJOR GROUPS, ALL MARKETS COMBINED

FISCAL YEAR	TOTAL	GRAIN	OILSEEDS/ PRODUCTS	LIVESTOCK/ PRODUCTS	OTHER AGRICULTURALS	ENERGY/WOOD PRODUCTS	METALS	FINANCIAL INSTRUMENTS	CURRENCIES
	AVERAGE MONTHEND OPEN INTEREST (IN CONTRACTS)								
1983	64,755	---	---	---	1,633	---	14,307	48,815	---
1984	283,184	---	---	---	2,887	---	58,500	193,114	28,683
1985	655,546	30,504	30,705	15,245	11,307	---	115,861	357,563	94,361
1986	1,111,628	57,128	52,676	35,537	30.208	---	122,642	596,274	217,163
1987	2,824,605	64,733	103,401	81,454	48,126	1,219,288	187,127	767,739	352,737
1988	2,009,893	105,959	131,234	88,456	111,545	210,503	175,304	757,571	429,321
1989	2,245,115	142,041	105,785	76,201	179,902	255,486	152,903	933,555	399,242
	NUMBER OF CONTRACTS TRADED								
1983	1,876,815	---	---	---	8,255	---	287,787	1,580,773	---
1984	7,953,528	---	---	---	9,157	---	1,190,636	6,267,653	486,082
1985	16,866,923	262,053	249,183	673,235	91,623	---	2,074,515	11,572,359	1,943,955
1986	30,459,630	592,126	871,302	758,973	282,498	---	2,153,821	22,021,891	3,779,019
1987	41,002,507	799,002	1,156,848	1,350,717	449,878	2,134,233	3,226,634	25,694,728	6,190,467
1988	49,029,200	1,685,479	3,283,359	1,497,313	1,563,923	5,268,867	3,377,251	24,833,999	7,519,009
1989	44,241,560	2,123,670	2,528,617	1,187,814	2,278,855	6,531,078	2,327,909	18,264,147	8,999,470

OPTIONS--AVERAGE MONTHEND OPEN INTEREST AND VOLUME OF TRADING FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	AVERAGE MONTHEND OPEN INTEREST (CONTRACTS)						VOLUME OF TRADING (CONTRACTS)					
	1987-88			1988-89			1987-88			1988-89		
EXCHANGE/COMMODITY	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL
CHICAGO BOARD OF TRADE (CBT)												
WHEAT	11,148	8,158	19,306	19,166	12,450	31,616	217,943	114,571	332,514	316,297	212,707	529,004
CORN	49,499	33,866	83,365	66,935	40,032	106,967	872,504	441,770	1,314,274	976,284	579,804	1,556,088
SOYBEANS	66,029	42,113	108,142	61,552	24,798	86,350	1,914,489	1,071,189	2,985,678	1,546,324	718,412	2,264,736
SOYBEAN OIL	4,859	4,634	9,493	5,831	2,468	8,299	70,300	53,908	124,208	75,270	29,942	105,212
SOYBEAN MEAL	5,705	6,076	11,781	5,707	2,759	8,466	85,569	68,179	153,748	94,092	47,369	141,461
U. S. TREASURY BONDS	252,495	241,795	494,290	264,771	254,217	518,988	10,347,189	10,024,010	20,371,199	10,576,012	10,066	10,586,078
U. S. TREASURY NOTES	28,495	25,090	53,585	25,849	28,970	54,819	537,898	464,681	1,002,579	572,141	560,448	1,132,589
MUNICIPAL BONDS	17,537	17,845	35,382	7,183	8,177	15,360	96,457	103,447	199,904	44,382	65,544	109,926
SILVER	859	80	939	960	387	1,347	7,632	1,116	8,748	6,131	2,006	8,137
MORTGAGE-BACKED FUTURES 1/	---	---	---	1,086	1,466	2,552	---	---	---	4,762	5,956	10,718
TOTAL CBT	436,626	379,657	816,283	459,040	375,724	834,764	14,149,981	12,342,871	26,492,852	14,211,695	2,232,254	16,443,949
KANSAS CITY BOARD OF TRADE (KCBT)												
WHEAT	2,200	840	3,040	2,147	770	2,917	26,550	9,714	36,264	24,729	10,149	34,878
TOTAL KCBT	2,200	840	3,040	2,147	770	2,917	26,550	9,714	36,264	24,729	10,149	34,878
COFFEE SUGAR & COCOA EXCHANGE (CSCE)												
SUGAR	65,024	20,530	85,554	84,565	39,133	123,698	1,085,015	261,560	1,346,575	1,270,901	446,672	1,717,573
COCOA	5,994	1,801	7,795	10,736	5,891	16,627	50,253	10,713	60,966	97,743	53,206	150,949
COFFEE	3,222	2,690	5,912	5,029	3,675	8,704	32,767	23,493	56,260	66,978	36,373	103,351
TOTAL CSCE	74,240	25,021	99,261	100,330	48,699	149,029	1,168,035	295,766	1,463,801	1,435,622	536,251	1,971,873
MIDAMERICA COMMODITY EXCHANGE (MCE)												
GOLD	3	2	5	69	36	105	30	29	59	249	202	451
WINTER WHEAT	21	47	68	105	188	293	172	219	391	584	1,106	1,690
SOYBEANS	983	835	1,818	1,847	823	2,670	13,914	5,811	19,725	9,530	7,678	17,208
TOTAL MCE	1,007	884	1,891	2,021	1,047	3,068	14,116	6,059	20,175	10,371	8,978	19,349

OPTIONS--AVERAGE MONTHEND OPEN INTEREST AND VOLUME OF TRADING FOR FISCAL YEARS ENDING
SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	AVERAGE MONTHEND OPEN INTEREST (CONTRACTS)						VOLUME OF TRADING (CONTRACTS)					
	1987-88			1988-89			1987-88			1988-89		
EXCHANGE/COMMODITY	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL
CHICAGO MERCANTILE EXCHANGE (CME) AND INTERNATIONAL MONETARY MKT. (IMM)												
LIVE HOGS	5,805	2,321	8,126	4,696	3,275	7,971	82,021	44,208	126,229	65,700	50,333	116,033
PORK BELLIES	654	232	886	1,877	925	2,802	7,226	2,720	9,946	22,795	16,050	38,845
LIVE CATTLE	33,291	33,168	66,459	27,652	25,874	53,526	616,884	561,538	1,178,422	491,061	394,816	885,877
FEEDER CATTLE	4,514	8,471	12,985	3,932	7,970	11,902	69,979	112,737	182,716	51,612	95,447	147,059
LUMBER	509	324	833	369	334	703	15,312	7,436	22,748	8,302	7,153	15,455
EURODOLLAR	61,590	74,051	135,641	144,795	147,649	292,444	1,148,234	1,212,165	2,360,399	2,669,653	2,694,480	5,364,133
BRITISH POUND	22,797	22,210	45,007	0	0	0	205,657	184,592	390,249	0	0	0
BRITISH POUND (NEW)	8,407	7,501	15,908	11,996	10,739	22,735	95,933	82,783	178,716	217,607	190,617	408,224
DEUTSCHE MARK	79,208	74,911	154,119	76,612	76,757	153,369	1,386,147	1,427,160	2,813,307	1,780,894	1,752,787	3,533,681
SWISS FRANC	32,196	29,246	61,442	31,310	29,648	60,958	578,225	557,678	1,135,903	688,627	729,471	1,418,098
JAPANESE YEN	66,231	74,310	140,541	59,216	75,696	134,912	1,315,269	1,496,750	2,812,019	1,435,995	1,865,366	3,301,361
CANADIAN DOLLAR	7,055	4,603	11,658	13,328	12,295	25,623	111,059	73,056	184,115	177,486	138,195	315,681
AUSTRALIAN DOLLAR	277	289	566	806	839	1,645	2,423	2,277	4,700	10,838	11,587	22,425
U. S. TREASURY BILLS	250	156	406	751	198	949	3,980	1,883	5,863	8,722	3,896	12,618
STOCK INDEX, S&P 500	17,224	16,954	34,178	18,642	26,715	45,357	442,766	393,868	836,634	451,134	547,944	999,078
TOTAL CME/IMM	339,888	348,947	688,835	395,982	418,914	814,896	6,081,115	6,160,851	12,241,966	8,080,426	8,498,142	16,578,568
MINNEAPOLIS GRAIN EXCHANGE (MGE)												
SPRING WHEAT	136	44	180	162	86	248	1,661	375	2,036	1,399	611	2,010
TOTAL MGE	136	44	180	162	86	248	1,661	375	2,036	1,399	611	2,010
COMMODITY EXCHANGE INC. (COMEX)												
GOLD	61,104	44,088	105,192	54,437	35,363	89,800	1,082,913	856,284	1,939,197	737,552	581,313	1,318,865
SILVER	32,273	12,266	44,539	34,318	12,727	47,045	690,471	226,914	917,385	482,074	196,367	678,441
COPPER	17,412	7,216	24,628	8,056	6,458	14,514	404,983	106,878	511,861	199,981	121,277	321,258
COPPER (HIGH GRADE)	1	0	1	68	24	92	1	0	1	677	80	757
TOTAL COMEX	110,790	63,570	174,360	96,879	54,572	151,451	2,178,368	1,190,076	3,368,444	1,420,284	899,037	2,319,321

OPTIONS--AVERAGE MONTHEND OPEN INTEREST AND VOLUME OF TRADING FOR FISCAL YEARS ENDING SEPTEMBER 30, 1988 AND SEPTEMBER 30, 1989

	AVERAGE MONTHEND OPEN INTEREST (CONTRACTS)						VOLUME OF TRADING (CONTRACTS)					
	1987-88			1988-89			1987-88			1988-89		
EXCHANGE/COMMODITY	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL	CALLS	PUTS	TOTAL
NEW YORK COTTON EXCHANGE & ASSOC. (NYCE)												
COTTON	8,418	3,371	11,789	16,623	13,356	29,979	66,372	30,374	96,746	186,208	110,931	297,139
ORANGE JUICE	160	335	495	281	613	894	659	2,717	3,376	3,161	6,682	9,843
US DOLLAR INDEX	340	95	435	161	31	192	6,490	4,511	11,001	1,565	438	2,003
US TREASURY NOTES	641	459	1,100	500	491	991	4,757	3,037	7,794	3,478	2,340	5,818
TOTAL NYCE	9,559	4,260	13,819	17,565	14,491	32,056	78,278	40,639	118,917	194,412	120,391	314,803
NEW YORK FUTURES EXCHANGE (NYFE)												
NYSE COMPOSITE INDEX	1,627	927	2,554	542	1,116	1,658	19,938	18,688	38,626	14,987	20,991	35,978
CRB INDEX 2/	---	---	---	150	95	245	---	---	---	3,639	1,569	5,208
TOTAL NYFE	1,627	927	2,554	692	1,211	1,903	19,938	18,688	38,626	18,626	22,560	41,186
NEW YORK MERCANTILE EXCHANGE (NYME)												
HEATING OIL	9,550	4,309	13,859	3,550	2,442	5,992	133,565	71,049	204,614	73,995	47,727	121,722
CRUDE OIL	91,932	103,879	195,811	97,136	131,817	228,953	2,216,489	2,825,016	5,041,505	2,778,436	3,344,712	6,123,148
UNLEADED GASOLINE 3/	---	---	---	9,921	9,917	19,838	---	---	---	141,786	128,967	270,753
TOTAL NYME	101,482	108,188	209,670	110,607	144,176	254,783	2,350,054	2,896,065	5,246,119	2,994,217	3,521,406	6,515,623
TOTAL OPTIONS	--------	--------	2,009,893	--------	--------	2,245,115	26,068,096	22,961,104	49,029,200	28.391,781	15,849,779	44,241,560
GRAND TOTAL FUTURES AND OPTIONS			4,837,867			5,415,918			290,789,955			311,899,950

STATISTICS TAKEN FROM DAILY DATA PROVIDED BY EXCHANGES

1/ TRADING BEGAN JUNE 16, 1989.
2/ TRADING BEGAN OCTOBER 10, 1988.
3/ TRADING BEGAN MARCH 13, 1989.

THURSDAY, MARCH 15, 1990.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

WITNESSES

JAMES S. BENSON, ACTING COMMISSIONER OF FOOD AND DRUGS

JOSEPH A. LEVITT, DIRECTOR OF EXECUTIVE OPERATIONS

MARGARET PORTER, CHIEF COUNSEL

SHARON SMITH HOLSTON, ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS

FRANK P. CLAUNTS, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT

JAMES O. MASON, M.D., DR. P.H., ASSISTANT SECRETARY FOR HEALTH

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. DURBIN [acting chair]. This session of the Subcommittee on Rural Development, Agriculture, and Related Agencies will come to order.

Chairman Whitten is on the Floor at the moment working on the Rural Development bill. We expect him to return, but we wanted to try to get on track here as quickly as we could.

I want to welcome the witnesses who are appearing this afternoon before our subcommittee.

First I would like to introduce and invite to make an opening statement Doctor James Mason, the Assistant Secretary for Health at the Department of Health and Human Services.

Dr. Mason, would you like to make some comments for the record?

Dr. MASON. Thank you very much, Mr. Chairman and members of the subcommittee. I am very glad to have this opportunity to appear before you in support of the Food and Drug Administration's budget request.

The Public Health Service, as you know, is committed to the achievement of better health for the nation's people through such efforts as disease prevention, health promotion, and the maintenance of a strong research capability.

FDA's regulatory activities are a unique and essential part of this overall effort of the Public Health Service. Its particular mission, directed toward the promotion and protection of the health of the American public, is essential.

FDA carries out its responsibilities through a wide range of activities. Product review, post-market surveillance, inspections, regulatory action, rulemaking, standard setting, and public education are all part of its responsibilities.

As you are well aware, FDA's efforts this past year were affected by revelations concerning unethical conduct on the part of a very small number of FDA employees and by several generic drug firms. I would like to assure all of you that FDA has been moving forward in implementing a comprehensive correction action plan which was announced by Secretary Sullivan last August. The key elements of that plan included intensified inspections, product sampling, and a reorganized and strengthened generic drug review process.

Fortunately, FDA's continuing investigations and those of others have not revealed any evidence to date that the public health has been jeopardized. I am confident that this will remain the case and that the agency will not rest until all public confidence in the safety and effectiveness of generic drugs is justifiably restored.

To help achieve this objective we are requesting a fiscal year 1990 supplemental of $13.9 million to be financed through the collection of user fees from the generic drug industry.

As with all of the Public Health Service, FDA remains committed to the conquest of AIDS by providing the most timely, effective, and efficient research and pre-marketing review possible of products that offer promise for diagnosing, treating, curing, or preventing AIDS or AIDS-related diseases, and by continuing to assure a safe supply of blood and blood products. To this end, FDA is requesting AIDS resources in their budget, which I fully endorse. There is no consolidated PHS AIDS request this year, as there was last year.

I am confident that FDA will continue to improve its ability to carry out its many responsibilities, to protect the consumer, and improve the public health.

The budget request before you would provide for increases to enhance FDA's capability, and I fully support that request. This year we are asking that industry support the cost of FDA's pre-market review activities. Since the sales of these products rely on FDA's ability to assure the public that they are safe, it is appropriate that the cost of determining that safety be borne by the industry.

Mr. Chairman, with your approval I would be pleased to have Acting Commissioner James Benson proceed at this time with his opening statement.

[CLERK'S NOTE.—Dr. Mason's biographical sketch appears on page 515. His written testimony appears on pages 516 through 517.]

Mr. DURBIN. Certainly. I welcome Mr. Benson. I think you have been at the table before—perhaps not front and center. We are happy to have you in that capacity and welcome your statement.

Mr. BENSON. Thank you very much.

I appreciate the opportunity to be here in support of our 1991 request.

Before I get started I'd like to introduce my support staff. Let me start down to my left: Frank Claunts heads up our Budget Office; Sharon Holston is our Associate Commissioner for Management and Operations, which includes the responsibility for budget; Chief of Staff next to me here is Joe Levitt; on my immediate right is Margaret Porter, who is Chief Counsel for FDA; of course, you have already met Doctor Mason; and Mr. Dennis Williams, who is Deputy Assistant Secretary for Budget from our Department level.

With your permission, sir, I will briefly summarize the statement without going into the details.

GENERIC DRUGS

As Doctor Mason said, the generic drug situation and the irregularities there made it a difficult year for FDA. I think the misbehavior of a handful of firms and three employees who have been accused and convicted of wrongdoing is an embarrassment to all of us and is something that we are anxious to get behind us.

I am pleased to say, though, that in general, our strongly increased testing has shown that the drugs on the market, including generic drugs, are safe. We don't like what happened, but we are pleased that the testing has shown them to be safe.

You have already provided us with some needed resources to assure that safety. I think with your continued support we will be able to further strengthen the generic program and, in fact, other programs across the board in FDA, as well. I think that those improvements will give us an even better guarantee of good, solid public health.

RESTORING FDA'S FIELD CAPABILITIES

The generic drug problem, combined with the Chilean fruit problem that we had last year, as well as some lesser crises, caused a lot of diversion of our field resources from their regular duties. In fact, if you look at the 1989 data, our domestic inspection rate was down some 32 percent from what it was five years ago. That was as a result of that diversion.

As we have looked at that over the years, it is not unusual to have those kinds of diversions all the time. We have got to do something to compensate for that. One of our major items in the budget for 1991 is a $12 million increase that would support 125 staff years to really allow us to begin to revitalize the field and be able to compensate for some of those diversions as they occur. I think that will take a large step toward getting us moving toward the surveillance level that we need.

AIDS

The AIDS area is another major challenge for us. Last year I am pleased to report that we approved six products for the treatment of AIDS or related problems. We were also able to, expand our distribution of several AIDS drugs before formal approval, as the community is very anxious to have us do.

Our AIDS increase request is less than last year's, but we believe it is essential to keep us on target for the rapid approval of AIDS drugs as those applications come in to us.

NEW DRUG REVIEW

I am pleased to report that we have made steady progress in many of our new product review system in terms of getting approvals out. In the new drug application area, for example, we were overdue on 67 applications at the end of the year. That is down from 71 the year before and down from 116 the year before that. We still have a way to go in that area but we are working on it and we think that is a significant improvement.

Perhaps even more dramatic, in the device area we had a record 7,000 notifications to market for devices last year. This is the so-called 510(k) program. I am happy to say that we had no overdue 510(k)s at the end of the year. We are trying to continue to whittle away at that backlog of products that need to be reviewed.

ORPHAN PRODUCTS

I want to also mention the fact that the committee has been concerned over the years with orphan products. Last year we approved nine orphan products. We had a grant program of $5.4 million that went to 21 recipients. In 1990 that grant program is increased to $7.5 million and we expect that will amount to 35 new grants in this fiscal year. Our budget request for next year sustains that level.

SEAFOOD MONITORING

Another major increase request is in the area of seafood where we are looking to an increase of $9 million in appropriated funds to enhance our inspection work, our sampling—both foreign and domestic, our research activities, and our support of State programs, especially in the shellfish area.

We look forward, with that enhancement, to an even safer seafood supply in 1991.

FACILITIES

Turning now to facilities. Our planning for a new AIDS building is proceeding. We were delayed in terms of getting that rolling, but I am happy to say the location has been specifically sited and that is on the road.

Our new building in Beltsville will be occupied by the end of the year. As I'm sure you remember, we have encountered a lot of problems in being able to occupy that facility.

Perhaps more important is our long-range need for a comprehensive plan for headquarters facilities. We are scattered in 23 locations throughout the metropolitan area. From 1990 funds, and working through GSA, we are preparing a detailed program of requirements that will lay the groundwork to be able to consolidate our headquarters operation. This is something that sounds mundane but is terribly important to us. It enhances communications. It allows us to grow. It allows us to add to staffs like the AIDS staff, when we need to. It has been a major problem over the years, so we are looking forward to working with GSA in that area.

USER FEES

Finally, I would like to note that I recognize from the past the committee's concerns about user's fees, but with the Federal deficit the way it is the Administration believes that user fees are an important way to reduce the burden on the taxpayer. I just want to let you know that I do support the Administration's decision on user fees.

With that I thank you. We would be happy to try to answer your questions.

[CLERK'S NOTE.—Witness biographical sketches appear on pages 518 through 523. Mr. Benson's written testimony appears on pages 524 through 538. The Food and Drug budget justifications appear on pages 539 through 653.]

Mr. DURBIN. Thank you very much.

I'll ask one question since I have got the gavel, and then defer to my more senior colleagues here. [Laughter.]

Mr. MYERS. You sure move up fast.

Mr. DURBIN. Yes, I'll tell you. You were back at the farm in Indiana and look what happened.

AIDS BUILDING

I want to ask you about the AIDS research center. I recall in 1988 that your predecessor, Doctor Young, came before this subcommittee with a crisis situation involving AIDS research. We all certainly understood this and tried to move as quickly as we could to respond to it.

One of the things that he asked for was $25 million to expand the FDA buildings for AIDS activities. In fact, I think this subcommittee went out of its way to help and included money in a supplemental appropriation bill to expedite that process.

As I understand it, it is some two years later and they have just—at this point your agency is just reporting that they have found a site for the building. Can you explain to us why there is such a delay in an area which I think most Americans would agree is a genuine crisis and one which this subcommittee was convinced at the time needed our immediate attention?

Mr. BENSON. I probably can't explain it adequately. I think the need was serious. It still is. We are happy that we have finally gotten through the bureaucratic process for getting the specific siting, which was a problem. The building has always been planned for the NIH campus. That is where it is going to go. It will be next to the two existing buildings that we have on the NIH campus for our biologics group. It just took a long time to negotiate that position.

Mr. DURBIN. So the negotiations were with the National Institutes of Health?

Mr. BENSON. Yes, the negotiations were with NIH, FDA, and the facilities people.

Sharon, you may want to flesh that out in more detail.

Ms. HOLSTON. Basically the negotiations were between the Food and Drug Administration and NIH as to where the appropriate site for the building should be, and it did take a while for us to resolve that question but it has been resolved as of the first of the year.

Mr. DURBIN. Well, we are certainly glad it has been resolved, but when you consider the gravity of this situation it just seems incredible that two Federal agencies spent a year and a half—almost two years—trying to decide on a location for a building. Usually it takes that long to make an initial commitment; once made, we try to move forward more quickly. I think in that period of time some other projects of this subcommittee have moved through to completion. When we are constantly being barraged with requests to expedite our work for new experimental drugs and efforts in research on AIDS, this is a very difficult situation to explain to most people—that two Federal agencies couldn't reach an agreement. Perhaps we can get into this a little more deeply at another time. We are all very interested in it.

At this time, Mr. Myers of Indiana, would you like to ask any questions?

AIDS

Mr. **Myers**. Always. Thank you, Mr. Chairman.

Whoever wants to answer this from the table of experts is welcome to: how many people die each year from heart problems in our country?

Dr. **Mason**. In the United States we lose each year approximately 700,000 persons to one or another type of heart disease.

Mr. **Myers**. How about cancer?

Dr. **Mason**. Probably about 500,000 a year.

Mr. **Myers**. That's 700,000 and 500,000?

Dr. **Mason**. Yes.

Mr. **Myers**. How about AIDS?

Dr. **Mason**. AIDS? Since the disease was first recognized in 1981 we have a little over 120,000 cases reported.

Mr. **Myers**. How many are we losing annually?

Dr. **Mason**. The total number of deaths are about 70,000 to date. Of course, the number goes up because of the number of cases reported. Probably this year, 1990, I would suspect that we will have about 25,000 deaths.

Mr. **Myers**. Now, how much money are we spending on research for heart problems?

Dr. **Mason**. For heart disease approximately $1.6 billion.

Mr. **Myers**. Billion?

Dr. **Mason**. Yes.

Mr. **Myers**. Okay. How about cancer?

Dr. **Mason**. I'm sorry. I gave you a figure for—in that same range. We're spending—what is that figure?

Mr. **Myers**. It is good to have help, isn't it?

Dr. **Mason**. It sure is.

Mr. **Skeen**. You ask questions too fast and it is hard to find all that. [Laughter.]

Dr. **Mason**. I was right on cancer, it is $1.6 billion, and heart is $1.1 billion in the 1991 President's budget.

Mr. **Myers**. And how much are we requesting for AIDS?

Dr. **Mason**. We are requesting $1.7 billion for AIDS, an increase of $109 million.

Mr. **Myers**. It doesn't make much sense, does it, when we are losing ten times as many people to heart disease and cancer, yet we are spending so much on AIDS and there is not a comparable loss as there is on the other two? How do you justify that?

Dr. **Mason**. I think it makes a lot of sense to do what we are doing. There are a number of differences between cancer and heart disease and AIDS.

First of all, the number of cases of heart disease have gone down every year for the past 17 years. In other words, the mortality rates are going down, and that——

Mr. **Myers**. Why is that?

Dr. **Mason**. That is because we have better coronary care units, we are not smoking as much, we are exercising more, we are eating better food that isn't as high in saturated fats. In other words, with cancer, which is level, heart disease, which is coming down——

Mr. **Myers**. It is level?

Dr. **Mason**. That is right.

Mr. **Myers**. That isn't the testimony we got the other day in the HHS Committee. What is going up in cancer overall?

Dr. **Mason**. The frequency per capita.

Oh, I think the only one that is going up is that associated with tobacco—particularly in women. But cancer is basically level.

Mr. **Myers**. Ten years ago 1 woman out of 11 would contract breast cancer, today it is 1 out of 10. That is what they told us.

Dr. **Mason**. Yes. Well——

Mr. **Myers**. That isn't going down, then, is it? That may be new math, but——

Dr. **Mason**. I was giving you the overall of 100 different cancers, not about specific types of cancer——

Mr. **Myers**. But I'm just using one as an example.

Dr. **Mason**. Well, some are going down; some are going up. Overall, cancer—what I want to say is, though——

Mr. **Myers**. The mortality rate is going down possibly, but the frequency of the disease——

Dr. **Mason**. The point is that the breakthroughs in AIDS have largely come about because of work that was done in cancer research. The research that is being done in AIDS will benefit us in cancer, heart disease—in other words, biomedical research is never so targeted. One of the major problems in AIDS is its damage to the immunological system, and the immunological system is basically the foundation for cancer and a whole series of other diseases.

Just like when we put a man on the moon. The spinoff of that technology helped our whole economy and helped us in many, many different areas. The spinoff for biomedical research as it relates to AIDS is right down the same track as cancer. And so I don't think we are detracting at all from what is going on.

There is another reason why we need to put money into AIDS, and that is that here is a disease that is going up. It makes a lot more sense to get in early, find out how the disease is transmitted, and begin to do something about it early on. That is a lot better than waiting. We think we have got about one million infected today, but if we sat on this we could have five million or ten million, with all of the consequences.

So when you have a disease going up like that, you want to get into it early and do something about it. Find out how to prevent it and how to treat it. Therefore, I think our budget is very appropriate for the magnitude of the disease and the way the figures are headed and how the spinoffs will help in a whole series of other chronic and acute disease states. This is a good investment for the nation. And it isn't one versus the other.

Mr. **Myers**. Absent the publicity and all the emotional side effects from whatever disease, if we gave you $5 billion, you'd distribute it more on AIDS than you would on either one of the other two?

Dr. **Mason**. I think you have to look at it in terms of what money may be available.

Mr. **Myers**. I'm saying that if we gave you $5 billion you would spend it that way?

Dr. **Mason**. If you gave me $5 billion and I had an epidemic of a disease that was——

Mr. **Myers**. I'm talking about what we have today in the country. You would still spend it more on AIDS than you would on either Cancer or heart disease research?

Dr. **Mason**. I would do exactly what we are doing. It is a good investment for the country, and if we don't do it then we will pay later.

Mr. **Myers**. Okay.

DRUG APPROVAL

Some of the pharmaceutical companies that I am familiar with are not going to continue to ask for whatever you call a trial.

Dr. **Mason**. An IND?

Mr. **Myers**. Yes, because of lawsuits that they have had and the judgments that have been leveled against them and the procedure taking so long to get a drug approved that they are just about ready to throw in the towel. Do you find that to be true?

Dr. **Mason**. I'd rather refer that to the Food and Drug Administration.

Mr. **Myers**. Okay. I'll bounce back and forth here. I'm coming back to you. Don't leave.

Dr. **Mason**. I intend to stay. [Laughter.]

Mr. **Myers**. Take a nap, if you'd like, but——

Mr. **Benson**. May I second that? [Laughter.]

Mr. **Benson**. I am not aware of any overwhelming concerns on the part of the developing companies. They haven't sensitized me to that issue. I'm sure that liability or litigation or any of those kinds of concerns are always present. There still seems to be activity in the area of developing new therapies. I feel like our responsibility in FDA, though, is to work closely with them, both in the very early stages of drug development in terms of helping them figure out what the appropriate tests would be, and we have made the approval of AIDS drugs and AIDS therapies, in general, the highest on our list. So we work very closely with the manufacturers to try to get those evaluations completed as fast as we can.

BIRTH CONTROL

Mr. **Myers**. Well, we had a great many lawsuits through the years for the effects of various drugs being used.

Mr. **Benson**. It is a problem.

Mr. **Myers**. It is not something you really can do much about, but it does mean that the patients of this country, the people that need to be treated, may not be getting the best. Now we are hearing some of our colleagues suggest that the reason we have a need for a higher incidence of abortions is because we are not affording the women of this country all of the birth control devices the rest of the world is getting and they lay the blame back often on your doorstep saying if you were a little more generous and did a little more examining that the women wouldn't have to have abortions.

One of the justifications that I hear my pro choice colleagues saying is, "Well, if you guys would get off your duff down there we wouldn't have to have abortions."

Mr. **Benson**. I think I am familiar with the report that may be the root of what you are saying.

Mr. **Myers**. RU-486. Isn't that one example?

Mr. **Benson**. Right. The report that I think the Institute of Medicine recently put out basically said there were two reasons for a slow-down in contraceptive research across the board in this country. The major one was litigation and the concern for companies getting the product onto the market.

So the answer—I don't know about the AIDS drug side of it so much, but I am aware of that fact.

They also mentioned some of the regulatory concerns.

But I think that, in context, the litigation issue far outweighs the problems. We have had a pretty good track record for approving contraceptives when they come to us.

I think it is ironic—and I'd like to just take advantage of this opportunity to say it is very easy to blame FDA for these kinds of problems.

Mr. **Myers**. I've done my share of it, too.

Mr. **Benson**. Join the club. I have too, I guess.

Mr. **Myers**. But that doesn't accomplish much. It really doesn't. It is counterproductive.

Mr. **Benson**. It makes us feel bad, but it doesn't accomplish much. You are absolutely right.

Dr. **Mason**. I just want to say there is no question that we need to be doing more contraceptive research in the United States. Thirty years ago this was looked upon as being one of the most promising technologies, and there were five or seven major pharmaceutical firms that were in the business.

As I understand it, in 1989 we are down to one in the United States, and that is——

Mr. **Myers**. Doing research?

Dr. **Mason**. Doing research. I'm talking about marketing—translating research and getting ready to put a product out so that they can submit a request.

And so we have seen, as the result of the litigation problem, a lot of companies just saying they don't want to continue to be involved in this. So I don't think the problem is basically FDA. Yes, FDA could do it faster, but as long as we have the litigation and malpractice problem in this nation I think there are a lot of companies that are not going to be willing to enter in and get involved in this area.

RU-486

Mr. **Myers**. For years we have been hearing about the morning-after pill. I thought there was some suggestion that it was just around the corner and maybe next year we would have the morning-after pill. Is there anything being done in this area? How likely are we to have a morning-after pill? Is RU-486 a morning- after pill, or is that an abortion pill?

Dr. **MASON**. I believe RU-486 is a pill that is given not the morning after, but several weeks after.

Mr. **MYERS**. Then it is an abortion pill?

Dr. **MASON**. It is an abortifacient. That is correct.

Mr. **MYERS**. But I wonder, are we going to have a morning-after pill some time in the future? Is there a likelihood?

Mr. **BENSON**. Let me ask Dr. Peck to come up and sit down and answer that. Carl Peck is Director of our Center for Drug Evaluation and Research.

Dr. **PECK**. Well, you know that RU-486 is not approved for any——

Mr. **MYERS**. Here in this country.

Dr. **PECK** [continuing]. In the United States at the present time.

Mr. **MYERS**. Is there any research being done in that area? Will it ever be approved or not, or can you say at this time? Has there been an application?

Dr. **PECK**. We do not have an application in hand for research as a contraceptive. It is being studied for some other——

Mr. **MYERS**. That's my next question.

Dr. **PECK**. Anti-steroid and anti-sex-hormone——

Mr. **MYERS**. It has been suggested as a possible treatment for, as I remember, infertility, glaucoma, and breast cancer. Is there any—are we examining any of those kind of things whether it could be used in these treatments?

Dr. **PECK**. The Institute of Child Health and Human Development does have studies underway looking at the effects of this in some diseases of the adrenal gland and other sex hormone conditions. But, to my knowledge, we are not aware of contraceptive uses.

Mr. **MYERS**. What about the other, such as Cushings Syndrome and infertility and glaucoma and breast cancer? Is there any possibility RU-486 could be used as a treatment in these diseases, among others? I think there were a number of them mentioned.

Dr. **PECK**. There is a possibility, and the National Institute of Child Health and Human Development does have studies underway looking at those.

Mr. **MYERS**. These are areas that we certainly haven't found solutions or answers for. So there is some possibility, then, that they could be right in this respect?

Dr. **PECK**. Yes, sir.

Mr. **MYERS**. But not as a birth control device?

Mr. **BENSON**. Mr. Myers, I want to make sure we are clear on one point, and that is that we do have IND applications that are standing for contraceptive uses. I think none of those are active at the present time.

Mr. **MYERS**. Okay.

Mr. **BENSON**. I want to make sure we are clear on that.

Mr. **MYERS**. Okay. But for treatment of other diseases there is some consideration, and there is a possibility at this point. You couldn't shut the door on that. But there would be no reason to bring it into the country at this point through legislation or anything else? Is that what you are saying? We are not ready to make that determination yet?

Mr. **Benson**. If someone wanted to conduct a study, that study could, under present situations, be done. And if someone conducted a study and presented it to us as a new drug application, then we would have to consider that just like we would any other application. That would be the status.

Mr. **Myers**. After all these years I guess I should know the answer to this question, FDA does not initiate studies except on pharmaceutical request?

Mr. **Benson**. That is a very strong generalization. FDA does not initiate studies for——

Mr. **Myers**. Then who does? Does it have to be a pharmaceutical company that would want to import RU-486 or get a license to use it? Is that how it would be?

Mr. **Benson**. Any manufacturer, foreign or domestic, can initiate a study, present us with an application, and so on—not necessarily for RU-486, but——

Mr. **Myers**. I use that as an example.

Mr. **Benson**. Exactly. The National Institutes of Health has a large budget that is aimed at drug development—therapy development across the board. So there is a sizable amount of Federal money that goes into product development. But FDA does none of that except in very isolated cases where we might encourage someone for a needed therapy. We certainly encourage those kinds of studies in the orphan product area with the grant money that I referred to in my opening statement. So to that extent we do support product research.

MAMMOGRAPHY

Mr. **Myers**. One last question. There are many, many clinics throughout the country who do laboratory work for diagnostic work. Are these clinics licensed? Who regulates them? I frequently hear that, using blood work as an example, a person can send the same blood samples to two or three different diagnostic labs and get different diagnoses. Why does that happen?

Mammography is an example. My wife had a bad experience with nobody being able to correctly read the mammogram. We, the patients, are depending upon the mammogram or lab test through a clinic, and yet we are not being adequately taken care of. How do we control that?

Mr. **Benson**. I think that is a very good question. I think the Clinical Lab Improvement Act of 1988 set forth some additional criteria that need to be implemented. Presently the responsibility for that rests with HCFA. It does not rest with the Public Health Service, nor with FDA, although we are assisting them in implementing wherever we can.

We have, however, done a lot of work over the years to assure that high quality mammograms are produced with the minimum amount of radiation exposure. Since many of the problems in this area are use related, where we have no regulatory authority, we have had to take an educational approach. We have worked closely with the State programs and with the professional organizations such as the American College of Radiology, which has developed a voluntary accreditation program for mammography facilities with our technical assistance.

The approach then has been an umbrella effort involving the Federal government, the State authorities, and the clinical profession—not only the physician organizations, but also the technologist groups who have a lot to do with really making sure that mammogram comes back in high quality.

Mr. MYERS. This committee is familiar with, as an example, stockyards. We make sure the grading of meat, of vegetables, and of produce is graded accurately. We make sure that the weight of grain and other products is appropriate. We have examiners and inspectors that go out and test and make evaluations.

People depend upon the mammography in the same way. My wife was getting mammograms faithfully and found out that the guy reading them didn't know what he was looking at. Do we make any evaluation to make sure the individuals who read the mammogram know what they are doing? Just going in and getting an X-ray isn't enough, evidently?

Mr. BENSON. As a matter of fact we initiated a program several years ago that dealt with a portion of this problem. I may mess up the acronym, but it is Breast——

Mr. MYERS. Well, there are a lot of them around to be messed up.

Mr. BENSON. I believe it was called Breast Exposure: Nationwide Trends Program or BENT. It was a program that——

Mr. MYERS. Go ahead and identify it, if you would.

Mr. BENSON. It was a program to detect facilities with problems preventing them from producing good quality mammograms and to help them solve these problems.

Mr. MYERS. You could have told me anything and I wouldn't have known. [Laughter.]

Mr. BENSON. Our credibility is important. We wouldn't do that. It is a program that was put together by FDA, the National Cancer Institute, and the State Radiation Control Programs. The sole purpose of that program was to make sure that the mammograms that were taken around the country were of high quality and taken with optimum radiation dose. The idea was that the facility would use just enough radiation to make sure you get a good, accurate picture. That program was not mandatory, except where a State would want to make it mandatory. But it was put into effect in 47 states.

Mr. MYERS. Well, the most up-to-date and latest state-of-the-art equipment can be used, but if the individual reading that X-ray cannot read it, the women going in and getting those mammograms are not being diagnosed correctly.

Mr. BENSON. I couldn't agree with you more, and I would also add to your scenario that the technologists that are running the equipment also need to know what——

Mr. MYERS. That is what I am talking about.

Mr. BENSON. Both the radiologist who reads the film, as well as the technologists that are producing the film, need to know what they are doing. It is very important.

Mr. MYERS. I apologize for taking the time of the committee here.

I will yield my time.

Dr. **Mason**. I think you are dealing with a very important area.

Mr. **Myers**. I found that to be true first hand.

CLINICAL LABORATORIES

Dr. **Mason**. In blood banks and that kind of laboratory services that is the responsibility of the Food and Drug Administration. In clinical laboratories across the nation, since 1967 Congress has had the Health Care Financing Administration look at clinical laboratories that are in interstate commerce and all those that are reimbursed by Medicare and Medicaid.

In CLIA in 1988, Congress prescribed that doctors' laboratories—a single doctor in his own laboratory would come under this kind of regulation.

When you get in to the practice of medicine, the reading of X-ray film is included in the context of the practice of medicine like listening to a heart or looking into the eyes or the ears. That falls under medical practice law, and that is entirely the responsibility of States. If there is a problem with the physician in terms of his conduct or his adequacy, that comes under either a specialty board or the licensure apparatus that each State sets up to guarantee the quality of medicine as it is practiced and as they annually or every other year license the physician.

So FDA can get in to the context of devices and make sure that the instrumentation is adequate, but the adequacy of the physician per se traditionally in the United States has been the responsibility of the States through licensure to oversee that.

Mr. **Myers**. I have taken a lot of time. I presume, though, the mammograms are read not by a physician but a technician, I would think.

Dr. **Mason**. They are read by a physician. A technician may look at them to judge for proper exposure factors and positioning, but it is the physician who has to sign off and report his clinical evaluation of what the mammogram demonstrates.

Mr. **Myers**. You mean the OB/GYN that orders the mammogram, the mammogram then goes back to that person?

Dr. **Mason**. No, ideally, and in nearly every case it is read by a radiologist.

Mr. **Myers**. The radiologist in the hospital or facility?

Dr. **Mason**. Yes.

Mr. **Benson**. I would add to that that in most States—I think in all States—the reading of a mammogram or any X-ray can be done by not only radiologists but other physicians. I think what is critically important with mammograms, as well as other diagnostics, whether it is X-ray or whatever, is that whoever does the interpretation has to have the proper training.

Mr. **Myers**. That is what disturbs me.

Mr. **Benson**. What is important is that the profession makes sure that the people that are board certified in radiology know what they are doing.

Mr. **Myers**. I have taken a lot of time. Thank you very much.

Mr. **Durbin**. Thank you, Mr. Myers.

MODULE I

We are going to have a vote, and it is going to be followed by another vote. So I'm sure it will take us away for the better part of a half hour. But before we—some of my colleagues have said they would like to return after the vote and continue the questioning, so I invite my colleagues, if they would like to leave and vote, to go ahead. I will ask another question or two to fill in a few minutes.

I wanted to ask specifically about Module I at Beltsville. Can you tell me a little about the history of this building? I am interested as to whether or not you have had any better success with Module I in terms of building it and occupying it.

Mr. **Benson**. I'm going to ask Sharon to answer you in detail, but the building has been completed, or for all intents and purposes completed. We refused to occupy it because of various deficiencies.

Sharon, would you like to add to that?

Ms. **Holston**. I would like to add that there were safety as well as environmental problems that we were concerned with. Once we determined that there were problems as far as structural deficiencies, air handling deficiencies, etc., I can enumerate a long list of horror stories associated with the building, but it was our position that the government would not be well served to accept a building that failed to meet the specifications in our construction contract. Therefore, we resisted occupying that building until we had assurances that it was corrected to the standards that we had requested in the first place.

I am happy to report that finally, after some negotiation with the parent company of the contractor that is actually constructing the building, we have reached accommodation. The work is proceeding now more speedily than it has for probably the past three years.

Mr. **Durbin**. The past three years?

Ms. **Holston**. Yes. And we fully expect to be able to occupy that building before the end of this year.

Mr. **Durbin**. I can tell you I have been on this subcommittee for six years and I am a big supporter of FDA. I have told the story often about a converted chicken coop that is being used by FDA. I have used that to justify to my colleagues FDA's requests for funds for buildings. But here we have two buildings with disastrous results in terms of construction.

I don't know whether the fault lies with your agency or whoever is responsible for construction, but to think that we have been negotiating literally for years to occupy a building which was supposed to be a high priority, and then, in another case, spend two years to find a location to build a building to look into an epidemic crisis across America, is troubling. I have to say I am wondering if the group that is responsible for planning and executing and building and supervising is doing as good a job as they should be.

Ms. **Holston**. I think, with respect to Mod I, I would like to say that I really don't believe it is the fault of the agency and that there is very little that the agency can do when contractors deliberately set out to defraud the government.

Mr. **Durbin**. Let me ask you point blank: have you turned this over to the Department of Justice?

Ms. **Holston**. We are working with the Department of Justice on issues related to the construction of Mod I.

Mr. **Durbin**. I won't go any further because I don't think that would help the situation.

Doctor?

Dr. **Mason**. I want to act as a heat shield for FDA because I really feel most of the problem for what you have talked about with both buildings are part of my office, the Assistant Secretary for Health. I think if we had given the Food and Drug Administration the support and the services that we are supposed to do they wouldn't have run into all those problems.

For example, I am over both NIH and FDA. This should not have been allowed to go on for two years. I couldn't agree more with you and I just have to apologize. I don't think it is FDA; I think it is me.

Mr. **Durbin**. That is very kind of you to accept that.

Dr. **Mason**. I want the blame to go where it should go because——

Mr. **Durbin**. I'm glad the record reflects that particular fact.

I might say to the panel and those in the audience it is unlikely we will return any sooner than 20 minutes—probably more likely a half hour.

At the request of the Chair, the subcommittee will stand in recess.

[Recess.]

Mr. **Whitten** [resuming chair]. The committee will come to order.

Go ahead, Mr. Durbin.

Mr. **Durbin**. Thank you, Mr. Chairman.

FIELD INSPECTION

Mr. Benson, I noticed in your testimony and the materials I have been given that the FDA has a substantial responsibility when it comes to inspections. If I am not mistaken, under the Medical Device Act of 1976 there is a requirement that your agency make periodic inspections of the producers of medical devices. Is it once every two years?

Mr. **Benson**. Yes. That is essentially correct.

Mr. **Durbin**. I also know that under current law by your own regulations required to make periodic inspections of food facilities. When I visited your Northeast Branch Office in Boston I was advised that they are able to make 330 inspections each year of food firms in the New England area. There are 2,600 food firms, so under the best of circumstances they can visit these food-producing facilities once every eight years. Of course, the explanation for the delays many times is due to things out of your control such as problems with tampering.

I also found some reference to an annual inspection of blood banks which is being undertaken by FDA. Some of the experiences I have had at your district offices indicate how important that work is and how it must continue.

And then I heard in your earlier testimony that you were going to take on generic drug inspections as another way of assuring quality in that industry.

I hear all of these, I look at your budget request, and I read that since 1984 your field monitoring inspections have decreased 32 percent. It seems that while you are taking on additional responsibilities for inspections, you have not kept up with the pace your own agency set back in 1984. I wonder if you have the resources or manpower to continue?

Mr. BENSON. The scenario you have laid out is complex, and I'd like to speak to several of the issues.

We have, in general, always tried to optimize whatever resources we had in a given area. You mentioned the bi-ennial inspection requirement in the device area. That is a requirement. It doesn't apply to all firms, but let's just assume it does for the sake of the discussion.

We have tried, for the firms that have a good track record compliance-wise, to make that a less intense inspection. For the firms that have a poor track record we make it a more intense inspection. So, in other words, we are trying to parcel our resources and target them to where they can do the most good.

In the foods area I am sure that the data that Ed McDonnell gave you was on target, knowing Ed. But the one in eight is not an adequate track record as far as I am concerned for food inspections. The only thing I would add is that we do a lot of programs in cooperation with the States. I would want to go back and see if some of those food firms weren't looked at by the States, which might make it a little better. But one in eight or once every eight years is not very good.

Again, I think we would concentrate on where we would predict or would expect to find some weak problems.

As far as the blood banks are concerned, I think that we used to do those every two years, and, as a result of concern for blood getting into blood banks that might have AIDS, we decided that we really needed to get in there on an annual basis and make sure that the blood banks were doing everything that they needed to do in order to assure a safe blood supply.

As far as the generic drug program is concerned, that is not a new program, but it is a highly-intensified one as a result of the problems that we had in the generic drug industry. They were under normal inspections, but what we have done is increased both the sampling for a product to make sure that it met the standards that existed, as well as targeting certain firms, going in and making sure that those firms were manufacturing up to good manufacturing practices. So clearly that is an intensified area.

As I mentioned in my opening remarks, our inspections are down 32 percent from 5 years ago, but a lot of that has to do with the shifting of resources to other areas.

For the fiscal year 1990 budget, you all allowed us about 150 extra additional FTE's that went to the field to enhance the inspection programs, and in 1991 we are looking for a total of 310 FTEs—full-time equivalents—to further enhance our field inspection work.

The bottom line to your question is what is adequate, and I think we'll have what is adequate when we can assure a safe set of products that we are responsible for.

Mr. DURBIN. This is an issue I am very interested in. First, let me say parenthetically, that Ed McDonnell and Frank Mizonni, who are up in your Boston Office, are excellent employees. We are lucky in the Federal Government to have people that dedicated and working that hard. I don't want to take anything away from them. They couldn't have been more open and candid during our inspection tour.

But it would be helpful to me if you would have someone in your budget office, or perhaps an agency, to construct what you consider to be your inspection requirements under law and assumed by your agency as against the FTEs available. Of course, then we are going to have to try to factor in the potential of a Tylenol tampering or a Chilean grape emergency, or whatever it might be that can divert your resources and manpower. But if we could see that, it might help this committee reach a conclusion on the adequacy of FDA's budget request.

Mr. BENSON. I would be delighted to provide that.

[The information follows:]

FDA INSPECTION RESOURCE NEEDS

FDA is required by law to inspect all processors (manufacturers, repackers and relabelers) of human drugs, animal drugs, medical devices, and blood products once every two years. By and large, with the increases projected for the field organization for FY 1991. FDA should have sufficient resources allocated to meet this requirement.

For foods, there are no statutory requirements for inspections of food establishments. With the increases projected for FY 1991, FDA is expected to have sufficient resources to support direct inspections and inspections performed by the States through FDA contracts which would allow domestic food establishments to be inspected, on average, about once every three years.

However, these estimates of inspection frequency assume that the Agency will not again have to divert large amounts of resources in FY 1991 to unplanned activities. For each of the last few years, FDA has had to divert about 400 FTEs to emergencies, such as Chilean fruits, and to other crises, such as generic drugs, which have prevented FDA from meeting the inspection timeframes discussed above.

There are many different opinions as to what level of resources would represent "adequate" inspectional coverage of the food industry. Adequacy of protection is a judgment that involves balancing the research available with skillful management of available resources, and there is no fixed number above which FDA can say that the level of public protection would absolutely be "adequate." We believe, though, that with the increases proposed for FY 1991, FDA will be able to move in a reasonable way toward rebuilding its field resources that will allow it to improve upon the level of protection currently provided the American consumer.

Mr. BENSON. Let me say that we have some data that we should be able to get out to you very rapidly. And I would also like to mention that, in large measure because of Dr. Mason's urging, we are going through what we call comprehensive needs assessment where we are laying out across the board what FDA's mission is and how we can address, with the resources we have, that mission. So we are going to have that data available. That is going to take some time, but we would be delighted to send that to you when we have the results of that program.

NATIONAL CENTER FOR FOOD SAFETY AND TECHNOLOGY

Mr. DURBIN. There are two other issues I will touch on briefly.

I just toured this week a facility in Bedford Park, Illinois, the National Center for Food Safety and Technology, that is being co-sponsored by the Illinois Institute of Technology.

I met with representatives of the FDA, as well as representatives of private industry who are helping to finance this effort.

I was very impressed, even though it is obviously in its earliest stages with what they are setting out to do. I hope that you share my feeling that this is a good investment, that the private sector involvement with FDA brings to it a special mix of talent and experience which can help us develop this field.

Mr. BENSON. I appreciate your comments. We look forward to some good results out of that facility.

THIRD PARTY ENDORSEMENT ON FOOD LABLES

Mr. DURBIN. If I could close on one issue that is controversial, I'd like to make sure there is a clear understanding on what is known as third party approval of food labeling, the suggestion of the American Heart Association and others that they would undertake some labelling to indicate to the American consumers that certain products were healthier from a heart disease aspect. As I understand it, the FDA is not wild about that suggestion. Can you tell me what your position is on that type of labelling?

Mr. BENSON. I would like to, but I am going to ask Joe Levitt to do that. That is one that he was working on.

Mr. LEVITT. Thank you.

Our basic position on the program, as we stated in a letter that we sent to the Heart Association in late January, is that we certainly agree with the goals of the program to provide nutrition information on food labels. We had a number of specific concerns with the way they are running their program. We listed those in our letter.

We have undertaken a wide-ranging food labeling initiative of our own with a number of public hearings last fall, with an announcement by Secretary Sullivan just a week ago, in an effort to try to get good information on food labeling for consumers and have that presented in a consistent and clear way to get the information out there.

Mr. DURBIN. Do I take it that at this point you are trying to encourage the Heart Association not to undertake this program? Is that as far as it has gone?

Mr. LEVITT. We have expressed strong reservations with their program, as stated in our letter.

Mr. DURBIN. And you are presently negotiating with them as to whether or not they will go forward?

Mr. LEVITT. We are continuing a dialogue with them on the subject.

Mr. DURBIN. Do you have legislative authority to stop any group from labeling a food product as healthy or good for your heart or good for your brain or whatever it might be?

Mr. LEVITT. We have general statutory authority to declare certain food products misbranded if we find their labeling false and misleading in any particular way. That would be the general authority that we would be concerned about in different types of third-party endorsement, which is the way we would refer to it—specifically, whether it is this particular one or another one. If you have two food products that have the same contents, but one, for whatever reason, has a particular endorsement and another does not, then we would have some concerns over whether the endorsement of one suggests it is better if, in fact, they are identical.

Mr. DURBIN. So it is safe to say that it is premature to suggest that you would use that authority at this point in relation to the Heart Association's proposed program?

Mr. LEVITT. We have stated to them in writing that, based on the way the program was proposed at that time, we may find one or more products with such labeling to be misbranded subject to review of particular cases.

Mr. DURBIN. Are any other associations or health groups considering the same thing at this moment?

Mr. LEVITT. There are a number of different groups that have varying degrees of ideas or programs in this area. One thing we are doing is an inventory of those and trying to take a broad look at it. We don't want to single out any one group; we want to be fair.

Mr. DURBIN. Does your agency have the resources to monitor these various groups that are looking into these endorsements?

Mr. LEVITT. We are making a strong effort to do so.

Mr. DURBIN. Thank you.

Thank you, Mr. Chairman.

Mr. WHITTEN. Thank you.

BUDGET REQUEST

Mr. Benson, we are glad to have you here and your associates. There are few, if any, groups in the government that have as hard an assignment as you have. Through the years I am very proud of the end results.

We also are aware from what we see in the press you have number of problems including indictments and what have you. We realize the complex assignment you have.

We have seen when—there are terminal patients where you would try to speed up the approval process. The drug companies are in it for business and they pass on to the customers their costs. Anybody who buys drugs knows that.

What we want to do now is to help you to handle your work better, if possible.

NIH and all these other institutes—it is wonderful what they are doing in the end result. But they don't have the same pressures that you do. They don't have to decide what can be and what cannot be used and what the conditions are.

Another thing that has been bothering me the last few years. Instead of the budget giving us a request big enough to meet your problems, it tells us to look to user fees. Several years nobody has even introduced the bills to establish user fees and yet you want us to accept it as a pre-drawn conclusion that the money will be available.

What did your agency ask of the Department of Health and Human Services in the way of funds? What was the total amount requested by the Food and Drug Administration for your own operation?

Mr. **Benson**. For the 1991 budget? Frank, do you have that? Maybe you could just kind of run through it for us.

Mr. **Claunts**. I have it right here.

Mr. **Benson**. This is Frank Claunts, whom you have met before, sir. He heads our Budget Office.

Mr. **Whitten**. How much money did you request?

Mr. **Claunts**. Our request to the Department of Health and Human Services was for $750 million and 8,585 FTEs.

Mr. **Whitten**. How much of this was allowed by the Department of Health and Human Services?

Mr. **Claunts**. Their request to OMB was for $696 million, sir.

Mr. **Whitten**. So they took a cut out of it and directed your attention toward $157 million which you would get from user fees. What leads you to believe—is that you, or did OMB tell you to look at user fees? When did that get in there, at OMB?

Mr. **Claunts**. There were some user fees proposed in our budget at a smaller level when it was originally formulated.

Mr. **Whitten**. You said "smaller level." What level?

Mr. **Claunts**. When our budget was originally formulated it was $16 million worth.

Mr. **Whitten**. That's $16 million?

Mr. **Claunts**. Yes, sir.

Mr. **Whitten**. When did you introduce a bill for this user fee?

Mr. **Claunts**. The user fee bill at this time is awaiting clearance at the Office of Management and Budget.

Mr. **Whitten**. Should we wait until then before we make the appropriations until it is reported?

Mr. **Claunts**. Hopefully it will be submitted soon.

GANOL

Mr. **Whitten**. You are a very optimistic person. We have heard that user fee proposal over and over.

May I say there are just a whole lot of things before the committee right now. The committee is in the situation of having the Administration ask for some money for additional foreign aid and not have anything in the bill there for the domestic situation. It is getting rough.

There are a whole lot of things that I could look back on. Years ago I had migraine headaches for years. There was a drug named Ganol—that's the popular name. They used it experimentally. They just let it go free as a bell. That was probably 30 years ago. But FDA at that time was uncertain whether the public could use it. It was o.k. for use all over Europe. The manufacturer is in Elizabethton, New Jersey, or was the last time I checked, and you never had made up your mind as to whether it was safe or not safe. Will you look up Ganol and see what you have done. That is the popular name. I don't know what the generic name is.

Mr. **Benson**. We would be glad to and let you know what the status is.

Mr. WHITTEN. If you will look at the record you will find this is about the fifth time we have asked for a report on that over the years.

Mr. BENSON. It is the first time you have asked me, but I'll make sure you get it.

[The information follows:]

GANOL

Ganol is a drug manufactured by the Schering Corporation but never marketed in the U.S. In 1977, Schering informed FDA that the drug may have been manufactured in the U.S. at some time prior to 1950, but only for sale outside the U.S., and that Ganol was being manufactured by Schering in a foreign plant, for sale in some Latin American countries. No application has ever been filed with FDA for approval of Ganol.

A label provided to FDA in 1953 by Congressman Whitten revealed that each tablet of Ganol consisted of a 0.4 gram combination of amino-pyrine, an analgesic antipyretic, and barbital, a sedative hypnotic. At that time, FDA regarded barbital as potentially habit-forming and considered amino-pyrine dangerous since it could cause granulocytopenia.

Policy statements concerning the lack of safety of aminopyrine or dipyrone were issued in 1964 and its use was restricted to serious or life threatening situations where salicylates or similar drugs were known to be ineffective, contraindicated, or not tolerated.

On June 17, 1977 approval of all NDA's for drug products containing dipyrone were withdrawn because reports of sometimes fatal agranulocytosis (also called granulocytopenia) had been associated with the use of dipyrone and because effective alternative drug products became available which reduced the potential for risk.

It is unlikely that aminopyrine or its derivative, dipyrone, will be the subject of a drug application because of a lack of evidence of safety for human use.

USER FEES

Mr. WHITTEN. That's the first time you faced us like this.

Mr. BENSON. That's right.

Mr. WHITTEN. We are not as negligent as you think.

Mr. BENSON. I don't think that.

Mr. WHITTEN. What are you going to do if Congress doesn't pass this user fee?

Mr. BENSON. Well, if the user fees aren't passed and the appropriation——

Mr. WHITTEN. Congress has turned it down right and left. In other words, why should a fellow pay a fee for using public findings? That is the attitude of the other side of it. Will you ask for a supplemental?

Mr. BENSON. This is a difficult issue. I think the decision——

Mr. WHITTEN. That is the reason I am asking the question.

Mr. BENSON. Yes, sir.

I think Dr. Mason wants to get a word in.

Dr. MASON. Mr. Chairman——

Mr. WHITTEN. You turn to the end man.

Mr. BENSON. He is my boss.

Dr. MASON. Congress directed the Department of Health and Human Services to try to find over $2 billion in user fees. We have been looking at areas where those people who use the products ought to also be willing to pay for the service that is required for that service. That is why we come to you with a request that of the $685 million, that $157 million of that be in user fees for 1991.

I want to also make it very clear that for our 1990 budget, to fix the problems with regard to generic drugs we need a supplemental in terms of user fees of $13.9 million. So it is not only in the 1991 budget, but FDA is very, very needful of $13.9 million as a supplemental for 1990.

Mr. **Whitten**. Is that pending? Have you requested it officially?

Dr. **Mason**. The request is official, and the——

Mr. **Whitten**. Under these conditions are you wanting us to change the law so as to offset it?

Dr. **Mason**. Yes.

Mr. **Whitten**. We are supposed to change the law so as to give it to you. What are you going to cut in your present——

Dr. **Mason**. For the——

Mr. **Whitten**. Do you spell out what we shall cut? Is it foreign or domestic?

Dr. **Mason**. No. What we would like you to do is authorize us to charge for both product review charges and maintenance fees in the generic area so that the employees at the Food and Drug Administration can ensure the quality of generic drugs—we are already hiring those people, and we need some way to pay for them.

Mr. **Whitten**. That is the Legislative Committee's business; we are Appropriations Committee. We don't have the authority to change the law.

Dr. **Mason**. But we hope that you will support this.

Mr. **Whitten**. Well, unless the authorizing Committee brings it to the floor we won't have the issue before us, despite your statement. It is all right to wish it, but the jurisdiction lies elsewhere. The Congress has spoken repeatedly against user fees. Why should the American people pay user fees so we can increase foreign aid?

Dr. **Mason**. All I can say is we need the $13.9 million as a supplemental to the 1990 budget.

Mr. **Whitten**. Have you requested it of the Office of Management and Budget? They'll send it up here if we will cut something else. Of course I read where they say we are going to take any increase out of Defense.

Mr. **Williams**. The supplemental request for 1990 is in the President's budget, so we——

Mr. **Whitten**. That's right, but then it is on condition that we change the law.

Mr. **Williams**. Yes, sir, that is true.

Mr. **Whitten**. Does it say what we should cut in order to make the additional funds available to you?

Mr. **Williams**. One of the reasons why we have supported user fees so strongly is that is——

Mr. **Whitten**. You give me a reason but no answer. You didn't give me an answer to my question.

Mr. **Williams**. By using——

Mr. **Whitten**. Did they give you information as to where we should cut in order to make the money available to you?

Mr. **Williams**. If we were authorized to collect user fees there wouldn't be any necessity to cut other parts of the budget.

Mr. **Whitten**. What others? That is what I am asking you. We have already established this Committee doesn't have jurisdiction over user fees so what did they say for us to cut? You will get the money if we cut something else. Did they identify what we should cut?

Mr. WILLIAMS. No, sir.

GENERIC DRUG STATUS

Mr. WHITTEN. Now, what have you done—turning to another subject, what have you done to solve these problems that we have read about? You might list in the record what problems you have had, what has appeared in court, what the standard is—I'll let you do that in the record. We will not advertise it here—and their present status of it.

Mr. BENSON. I would be glad to do that.

Mr. WHITTEN. As far as names are concerned, you can leave those out. I don't like to use names unless we give those named a chance to say the other side. Just bring us up to date.

[The information follows:]

GENERIC DRUG INDUSTRY AND FDA

In June, 1988, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce referred to the Office of Inspector General (OIG), Department of Health and Human Services, allegations of misconduct in the generic drug review process within the FDA. The information alleged (1) possible acceptance of gratuities from pharmaceutical companies by employees of the generic drug division of FDA, (2) potential fraudulent statements in applications for approval to market generic drugs, and (3) possible drug substitution in the course of the approval process. The Commissioner of FDA concurred with the Subcommittee's position that the Department's investigation of these charges should be conducted by the OIG.

OIG's investigation of FDA's internal policies and operations was brought to the attention of the United States Attorney for the District of Maryland, under whose auspices this investigation proceeded to prosecution since matters indicating a violation of Federal law were involved.

As of March 1, 1990, criminal investigations have led to the convictions of:

Three chemists within FDA's Division of Generic Drugs who pled guilty to acceptance of illegal gratuities from generic drug company representatives and have subsequently been sentenced to incarceration in work release programs, periods of probation, fines, and the performance of community service. None of the individuals remain with FDA.

Three presidents of three separate pharmaceutical companies, Par Pharmaceuticals, Inc., Quad Pharmaceuticals, Inc., and Pharmaceuticals Basic, Inc., who pled guilty to paying illegal gratuities and were subsequently sentenced to incarceration in work release programs, periods of probation, fines, and the performance of community service.

Two of the companies, Par Pharmaceuticals, Inc., and Quad Pharmaceuticals, Inc., who, as corporate entities, entered guilty pleas based on the actions of their corporate officers and were subsequently fined.

On March 1, 1990, criminal charges were filed against three individuals and a corporation in connection with the continuing investigation of the generic drug industry. Charged were the former chief executive officer of a generic drug company with two counts of Interstate Travel or Use of Interstate Facilities in Aid of Racketeering, the company, American Therapeutics, Inc., a generic drug consultant who, on behalf of his company, Pharmagen Consultants, alledgedly paid illegal gratuities to two FDA employees, and a former employee of the Food and Drug Administration who alledgedly accepted an illegal gratuity. Pleas of guilty were entered by the consultant on March 16, by the former FDA employee, the former chief executive officer, and American Therapeutics, Inc. on March 30, 1990.

On April 12, 1990, charges were filed against a former president of My-K Laboratories, Inc. in connection with an unlawful cash payment to a former FDA official. At this time, the Attorney's Office noted that while the initial focus on the generic drug industry was related to corruption matters—the providing of cash and items of value to FDA employees, the investigation has expanded to include additional allegations of product substitution, fraudulent documentation of manufacturing records, and the obstruction of FDA regulatory inspections. Additional corruption charges, and the first fraudulent production charges, are to be expected within ninety days.

Ongoing investigations have uncovered evidence that other generic drug companies had been submitting falsified data and bogus drug samples to FDA. As a result of these and other misrepresentations, certain generic producing drug firms actuated product recalls or suspended manufacturing operations altogether. FDA has made a number of drug approval withdrawals. Combined efforts of the FDA and OIG have resulted in numerous products being recalled from the market.

FDA is implementing a corrective action plan which was announced by the Secretary of the Department of Health and Human Services in August, 1989. This plan has two objectives: to assure safety and effectiveness of generic drugs; and to assure fairness in the generic drug review process. These objectives are to be achieved through the conduct of an intensified analyses of generic drugs and firms, reorganization and strengthening the generic drug review process, establishment of an independent Ombudsman to resolve disputes, and the preparation of new legislation to strengthen and clarify authority to act against improper activity in connection with generic drug applications. FDA is working with the OIG in an effort to tighten regulatory mechanisms to insure that such incidents do not occur in the future, recognizing that internal FDA reorganization, and possible law changes, may be needed to fully restore confidence in the generic drug market.

Mr. WHITTEN. What can we do to help you to straighten up some of the things that have become evident?

Mr. BENSON. I can summarize it now if you'd like very quickly.

Mr. WHITTEN. Please do.

Mr. BENSON. We have added resources at headquarters. We have added resources in the field. The headquarters resources are to make sure that the product reviews and the science that those reviews are based on is sound. In the field we have increased our sampling and we are doing more chemical analyses, more inspections of the firms—especially those firms that have been found to be guilty of some wrongdoing. And we are doing more across-the-board inspections and asking deeper questions in the firms, themselves. That is all costing, and at present I think you allowed us $4 million in this year, which we are using in this area. We have actually borrowed from other areas. The reason for the supplemental for this year is to augment that.

I think I can answer your earlier question. The authority is requested for the generic drug user fees in the appropriations request. That was the way it was handled.

Mr. WHITTEN. Well, you understand, as I mentioned earlier, we have some limitations, ourselves. A couple of years ago we had a continuing resolution because the other body was unable to get through with its work in time.

Mr. BENSON. I understand.

Mr. WHITTEN. Because of that we were able authorize and appropriate, but normally you don't. We have to wait until a legislative committee——

Mr. BENSON. I understand.

NEW DRUG APPROVAL PROCESS

Mr. WHITTEN. Two or three other things through the years have been issues here. One was whether you took too long to make up your mind on some of these drugs, and another was whether you located at the better-known countries—England, Germany, and these others—where they had drugs being used but not allowed here. Are you in position to use any of foreign countries results or have a speedy test? As I said, I have learned from here that in the past if a drug doesn't do any harm, then they go ahead.

Now, in recent years we are way behind in our trade deficit. we have opened up our doors to just about anything. In turn we have held up selling our goods in foreign countries. Since we have started that practice we just have no excuse not to take advantage of those countries that are way ahead of us. Do you have any way you can speed up the testing of accepted drugs from other countries? Do you have a group whose job it is to keep up with world conditions so we might have a speedy test to make them available? Do you have such a group?

Mr. **Benson**. We don't have a group that is dedicated to looking at foreign data and the use of that data to speed up the process, but we have a system—and especially this has been done for AIDS drugs and for cancer drugs, drugs for life- threatening or deeply debilitating diseases—to make sure that they get the highest priority and, in fact, are reviewed as swiftly as we possibly can.

As far as the use of foreign data, there is nothing wrong with using foreign data for an application.

Mr. **Whitten**. How fast do you approve it? Do you ever fast-track where you can check it right off?

Mr. **Benson**. I'm going to let Mr. Levitt answer more fully, but the answer is yes, we do have a fast track in one of those areas.

Mr. **Whitten**. Let's get a report in the record as to how long it takes you on various drugs to reach a conclusion—particularly those that are used in foreign countries that you are aware of.

Mr. **Benson**. We would be glad to do that.

[The information follows:]

Analyses of New Drug Development and Review Times With Emphasis on Differences Between U.S. and Foreign First Approvals

The Food and Drug Administration has conducted two recent analyses that provide data on the effect of foreign experience on U.S. drug development and approval time. The first looked at the approval times (elapsed time between New Drug Application (NDA) submittal and NDA approval) of 199 new molecular entities (NMEs) approved between 1980 and 1989. The average approval time for the 113 drugs approved in foreign countries prior to NDA submission in the U.S. averaged 33 months, and the average approval time for the remaining 86 drugs that had not been approved abroad at the time of NDA submission averaged 34 months.

The nearly equal approval times for these two groups, are obscured by additional factors that affect drug approval times, such as therapeutic significance, class, and past experience. In this study, multiple regression analysis was used to control for and test some of these factors and the following three variables were found to be significant:

(1) The therapeutic significance of the drug shows a strong relationship to the drug's approval time. Drugs that provide an important therapeutic gain over existing medications spent an average of 12 fewer months in the approval process than those drugs providing little or no therapeutic gain. Drugs that provide only moderate therapeutic gains over existing medications were approved an average of 9 months faster than the marginal drug.

(2) Certain thereapeutic classes of drugs spend more time in the NDA review process than others. The analysis looked at drugs for the cardiovascular system, central nervous system (CNS), and anti-infectives. The average approval time for a CNS drug was 17 months longer than that of an anti-infective. The average approval time for a cardiovascular drug was 12 months longer than that of an anti-infective.

(3) The number of years of a drug's prior foreign experience is associated with a modest decline in NDA review time. On average, drugs available in a foreign country 5 years prior to an NDA submittal were approved more than 2 months faster

than drugs obtaining foreign approval at about the same time as the NDA submission.

Other factors considered in this analysis of approval times included the year of NDA approval, the experience of the firm that sponsored the NDA (defined as the number of other approvals between 1970 and 1987), and the nationality of the sponsoring firm. None of these factors were statistically significant.

The second study took a broader perspective of the drug development process, and found that foreign experience may have its most significant effects on the earlier clinical research phases of drug development. The study sample included all 174 NMEs for which original Investigational New Drug Exemptions (INDs) were submited during the period 1976–78.

A drug approved in a foreign country prior to NDA submittal in the US consumed an average of 109 months from first IND submittal to NDA aprroval. Drugs that were not foreign-approved averaged about 118 months. Thus, foreign-approved drugs took nine fewer months to progress from their IND submission to regulatory approval.

A closer look shows that the IND phase accounts for all of the relatively shorter time taken by the foreign-approved drugs in the sample. While taking about 5 months more after an NDA had been submitted, foreign-approved drugs averaged about 14 months less during the IND period. This is at least partly explained by FDA's acceptance of foreign data. Over 35 percent of these foreign-approved drugs utilized foreign dose-ranging studies to satisfy their Phase 1 testing requirements. Similarly, about 30 percent of the successful foreign-approved drugs utilized foreign data for a subsequent IND phase.

These studies suggest that numerous factors affect the time period needed for drug development and approval. In general, however, the data indicate that foreign experience typically expedites the overall drug development process.

Mr. WHITTEN. I ask this because something needs to be done. Let me switch subjects. We gave a nickname to one of your predecessors, Mr. Gardner.

Mr. BENSON. I remember.

Mr. WHITTEN. Mr. Gardner had his head down—I would say this for the record—he told us you had changed the definition of zero. I asked him a serious question and he kept looking down and finally it dawned on him what he said. But the point of it is that now there doesn't seem to be any such thing as zero.

But the point I make is that because of new technology there is probably still detectable signs in the air from the Chicago fire and the turbulence from the San Francisco earthquake of many, many years ago. There is no such thing as zero, as such.

We have wrestled with the Delaney Clause for years. Mr. Delaney agreed that we should modernize it and just keep his name on it. But I never could get the legislative committees to do that.

In so many of the tests that are reported to us they don't go into how much quantity it would take to cause the outcome. Is there any way to see that researchers give us a report on the necessary quantity before they come out with something that scares the public about the use?

Mr. BENSON. I believe very strongly in not scaring the public inappropriately, and I think we need to do more in the way of helping the public understand what risks they are exposed to. I fully agree with you there.

There are some areas under our jurisdiction where we aren't chasing zero, where we have an opportunity to make decisions based on reasonable risk/benefit analyses.

Mr. WHITTEN. You understand we are for safety, ourselves.

Mr. BENSON. Absolutely.

Mr. WHITTEN. We are not trying to get you to cut corners. But it is better to lay it all on the table and make the judgment with that in sight.

DELANEY CLAUSE

Mr. WHITTEN. Mr. Benson, recently the Secretary of Health and Human Services, Dr. Sullivan, announced the termination of the provisional uses of a color additive. But in so doing, he was very clear in stating that the risk posed is extremely small. Secretary Sullivan noted that the National Academy of Sciences has recommended that the Delaney Clause be replaced with a Negligible Risk Standard. Over the years, this Committee has been concerned with the fact that the Delaney Clause was based on a zero tolerance standard and that technological advances over the years have basically made it impossible to have a zero tolerance. Will the Administration propose legislative language to change to a Negligible Risk Standard?

Mr. BENSON. The Administration has begun this process. In February and March of this year, the Administration provided technical assistance and legislative language for this purpose to several members of Congress from both parties. This proposal would establish a "negligible risk" standard for pesticide residues in foods and eliminate a long-standing inconsistency in the law governing such residues. This inconsistency, the "Delaney Paradox," is that the Delaney clause applies to pesticide residues in processed foods, but not to residues in raw agricultural commodities. This proposal was first announced on October 26, 1989, when President Bush released his Food Safety Plan, calling for major revisions to the Federal Food, Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. The joint statement released by HHS, USDA, and EPA on that occasion also recommended that the negligible risk principle be applied to "other areas of food safety where additives are introduced into food."

RED DYE NO. 3

Mr. WHITTEN. In the fiscal year 1974 Appropriations Report the Committee had asked the Food and Drug Administration how much of a banned substance a human would have to consume to equal the amounts given experimental animals. For the record, please submit similar examples for red dye No. 3 and four or five other recently banned food or color additives.

Mr. BENSON. Of the most recently banned color additives, FD&C Red No. 3 is the only one that has food uses. Other color additives that were banned recently are D&C Orange 17, D&C Red No. 19, and D&C Red Nos. 8 and 9. For FD&C Red No. 3, the highest dose fed to rats was four percent of their diet which corresponds to 120 grams per person per day or 2 gm/kg for a 60 kg person. Using information on the levels of the color used in some candy the agency calculated that a person would have to consume about 1.5 million grams, about 30,000 two-ounce packages, of that candy per day to reach the same dose as fed the animals. However, a more relevant number might be the amount of that candy a person would consume at the one in a million risk of cancer dose. For FD&C Red

No. 3 this figure, about half a milligram per day, would be reached by consuming one 2-ounce bag of candy per day over a lifetime.

As I do not have data on usage of the other recently banned color additives in food, I would like to submit a chart to compare the doses tested with FD&C Red No. 3 and the estimated dose that would provide the one in one million lifetime risk.

[The information follows:]

Additive	Date banned	Dose tested [1]	1 in 1 million lifetime risk dose
FD&C Red No. 3	Jan 29, 1990	4 percent (2.2) g/kg)	8 μ/kg/day
D&C Red No. 19	July 15, 1990	0.1 percent (0.05 g/kg)	0.3 μ/kg/day
D&C Red Nos. 8 and 9	do	0.3 percent (0.15 g/kg)	1.6 μ/kg/day
D&C Orange No. 17	do	1 percent (0.5 g/kg)	2.1 μ/kg/day
Cinnamyl anthranilate	Oct 23,1985	1.5 percent (2.3 g/kg)	0.7 μ/kg/day

[1] Percent of the animal test diet (grams/kilogram body weight)

USER FEES

Mr. Whitten. Again this year a major portion of the Food and Drug Administration operating expenses during fiscal year 1991 are to be derived from user fees. You have indicated that you would collect $157,175,000 from different aspects of the industries regulated by the Food and Drug Administration. Your appropriation language requests only $527,997,000 in appropriated funds. It is disappointing that the agency cannot request appropriation language based on current law as was recommended in both the House and Senate reports. In response to the Committee's suggestion, you have stated, "Congress endorsed a government-wide collection target of $2.7 billion worth of user fees in the Bi-partisan Budget Agreement for fiscal year 1990." Please explain the relationship of the Budget Agreement for fiscal year 1990 with the appropriations request for fiscal year 1991.

Mr. Benson. While there may not be a direct relationship between the agreement for fiscal 1990 and our request for 1991, the purpose of noting the 1990 agreement in our justification was simply to note that Congress has supported user fees as part of the overall effort to reduce the deficit.

We are aware of the Committee's guidance on user fees, but the Administration continues to believe that user fees, where industry benefits substantially from governmental activities, are an appropriate and important way to pay part of the cost of those activities, and that there is support in Congress for this concept.

Mr. Whitten. The Rural Development, Agriculture, and Related Agencies Appropriation Bill contains over 30 agencies and many, many more separate appropriations accounts. All other agencies that indicated collections from user fees during fiscal year 1991 requested current law appropriations language and assumed collections of user fees elsewhere in the budget process. Why it is FDA is the only agency within this bill that cannot do that?

Mr. Benson. The President's Budget accurately presents the resources required to fulfill FDA's mission in 1991. FDA and the Administration continue to believe that the direct beneficiaries of government services should finance those services through fees; moreover, user fees represent a unique opportunity to improve the quality and efficiency of FDA operations.

Mr. WHITTEN. If sometime during fiscal year 1990 Congress were to provide legislation specifically authorizing user fees for the Food and Drug Administration, specifically for drugs, devices, food additives, and others, how long would it take the Food and Drug Administration to promulgate rules and regulations, publish them and make final the rules under which it would collect user fees?

Mr. BENSON. I believe we could publish a proposal very soon after a law was passed. Allowing for a suitable public comment period and for agency review of those comments, it would probably take another several months to publish a final rule setting out the fees. Much would depend on the final form of such legislation as Congress passed it.

Mr. WHITTEN. Is your total request for user fees of $157,175,000 based on collections beginning October 1, 1990?

Mr. BENSON. Yes.

Mr. WHITTEN. Your budget request also includes 1990 supplemental appropriations language to collect $13,900,000 of user fees from generic drug related work. Is the amount requested based on collecting for the entire fiscal year, or at what point in time does it assume you would begin collecting to receive this amount?

Mr. BENSON. The proposal was based on beginning collections approximately halfway through this fiscal year. Fees for monitoring activities are proposed to be collected as an annual fee to holders of approved Abbreviated New Drug Applications, and this fee could be collected on a designated date during the latter half of the fiscal year. Fees for new generic drug applications would obviously have to begin after the implementing regulation is published, so the collections from those fees would depend on when we start to charge.

AIDS BUILDING

Mr. WHITTEN. In fiscal year 1989 Congress provided $22.5 million to begin construction of a Food and Drug Administration facility at the NIH campus to house FDA employees working on AIDS issues. Prior to that, the Committee had directed that $2.5 million from existing unobligated balances be used to begin the planning process. We have requested that the Secretary of Health and Human Services submit quarterly reports regarding the status of this new AIDS building. As of yet, we have received no information. When do you expect to submit this report and bring us up to date at this point on what has happened with that building?

Mr. BENSON. A report will be forthcoming soon.

[CLERKS NOTE.—Subsequent to the hearing the FDA submitted a report to the Committee on March 22, 1990. A copy of the report follows:]

REPORT FOR HOUSE AND SENATE APPROPRIATIONS COMMITTEES

PROGRESS REPORT ON FDA AIDS BUILDING

In its Report (House Report 101-137) on 1990 Appropriations for FDA, the House Appropriations Committee expressed concern over delay in planning for FDA's new building for AIDS work to be located at the NIH campus, and requested a quarterly report on the status of this building. The Senate Appropriations Committee expressed the same request in its Report. (Senate Report 101-84). This report is in response to those requests.

The new FDA AIDS Building, to be known as Building 29B, will be constructed on a site west of existing Building 29A on the NIH campus. Most of FDA's Center for Biologics Evaluation and Research staff is currently housed in Buildings 29 and 29A, which are adjacent to each other. The new building will provide approximately 50,000 net square feet of usable space and house 100 laboratory personnel and 60 office based personnel. This will enable FDA to house almost all of its Biologics AIDS-related laboratory staff very close together.

FDA's 1989 appropriations provided $25 million for this building ($22.5 million from new appropriations, and $2.5 million from prior year unobligated balances). NIH facilities management staff are managing the design and construction for this facility. Solicitation of interest by architectural firms was published in early March, 1989.

Completion of the Program of Requirements (POR) and development of concept drawings for the new building have been delayed by the site selection process. On January 17, 1990, NIH and FDA agreed on the west site and on the general conditions that will govern use of that site. POR completion is now anticipated by mid-1990.

The contract for design of the building should be awarded by mid-summer 1990, and the design should be completed during the last quarter of 1991. Following the process of awarding a construction contract, construction should begin in early 1992 and should be completed in the second half of 1994 or early 1995.

Mr. WHITTEN. Have there been any changes to the estimated cost of this facility? When will you notify Congress and request these funds?

Mr. BENSON. We are continuing to examine the projected costs of the facility, with the assistance of NIH staff who are managing the design and construction of this building for FDA. NIH staff have indicated their belief that the facility's total costs may need to be as much as $3.5 million more than the $25 million provided by the Congress in 1989 appropriations action. We are currently evaluating these concerns, and will advise the Appropriations Committee if it is determined that any of our 1990 Buildings and Facilities appropriations will need to be devoted to this project.

Mr. WHITTEN. What is the status of the engineering and design plans for the facility?

Mr. BENSON. Completion of the Program of Requirements and development of concept drawings for the new building have been delayed by the site selection process. Analysis of the several sites considered for the building took much longer than anticipated. Finally, on January 17, 1990, NIH and FDA agreed on the west site and on the general conditions that will govern use of that site.

The contract for design of the building should be awarded by mid-summer 1990, and the design should be completed during the last quarter of 1991. Following the process of awarding a construction contract, construction should begin in early 1992 and should be completed in the second half of 1994 or early 1995.

AIDS BUILDING

Mr. WHITTEN. Considering this was requested and justified as a serious matter, why has so little been done towards construction? You testified that you have just resolved the location of the facility. Considering the fact that Congress expedited this work in fiscal year 1988, do you consider that resolving the "precise site" for the building in 1990 as expedited work?

Mr. BENSON. No, it should have been resolved sooner. We appreciate the fact that Congress responded to this need and provided funds that were available to us in the latter half of calendar 1988. Most of the preliminary planning work with NIH has been done, however, and the precise location of the building does have an important effect not only on FDA's work but on the infrastructure and traffic flow on the crowded NIH campus. We regret that these issues were not resolved earlier so that the actual design of the building could have begun during 1989.

NATIONAL COMMISSION ON ORPHAN DISEASES

Mr. WHITTEN. The Committee has requested that the Food and Drug Administration review and respond to the recommendations contained in the report of the National Commission on Orphan Diseases. This report was due to the Committee before December 1, 1989. You have indicated that the report is complete. When can the Committee expect your responses?

Mr. BENSON. The National Commission on Orphan Diseases observed that, in spite of the increasing number of drugs designated for study for the treatment of rare diseases, there continues to be a lack of knowledge about and lack of treatment for rare diseases. The FDA agrees with this position and is working very closely with other health agencies, the pharmaceutical industry, and academia to find practical solutions to address the problem. The recommendations of the Commission are pertinent to this effort and support us in this high priority activity. Implementation of many of the recommendations has already begun in FDA.

The report is in final clearance and will be transmitted very shortly.

FOOD LABELING

Mr. WHITTEN. In November and December of last year the Food and Drug Administration held a series of public hearings concerning food labeling. Do you expect any more hearings during 1990?

Mr. BENSON. As a result of an advance notice of proposed rulemaking published in the Federal Register of August 8, 1989, FDA held public hearings in Chicago on October 16, San Antonio on November 1, Seattle on December 7, and Atlanta on December 13. Following those hearings, FDA published a reproposed rule on health messages for foods on a series of food labeling issues in the Federal Register on February 13, 1990. Other proposals for food labeling reform are planned for publication through 1990 into 1991. Since each proposal will allow a period of time for submission of comments, there is no perceived need to schedule and conduct additional public hearings during 1990. Accordingly, there are no plans for public hearings in 1990.

Mr. WHITTEN. In conjunction with that same effort, the National Academy of Sciences is preparing a White Paper concerning food labeling changes. When do you expect to receive their work?

Mr. BENSON. The National Academy of Sciences' effort on food labeling is being conducted under contract through the joint sponsorship of the Department of Health and Human Services and the U.S. Department of Agriculture. The terms of the contract require that a final report be submitted by the National Academy of Sciences by September, 1990.

BUDGET REQUEST

Mr. **Whitten**. Your budget explanatory notes and justifications for fiscal year 1991 show comparisons to fiscal year 1990 that include the $13.9 million supplemental requested. At this time no such supplemental has been granted. For the record, please submit a new object class table showing fiscal year 1990 estimates without the $13.9 million request.

Mr. **Benson**. I would be happy to provide that information for the record.

[The information follows:]

OBLIGATIONS BY OBJECT CLASS

[In thousands of dollars]

	1989 actual	1990 estimate	1991 estimate
Personnel compensation:			
Total personnel compensation	279,606	305,731	358,014
Personnel benefits	49,836	53,953	63,180
Benefits for former personnel	4	10	10
Total personnel, compensation and benefits	329,446	359,694	421,204
Other objects:			
Travel and transportation of persons	11,596	13,631	14,960
Transportation of things	1,534	1,704	2,037
Standard level user charges	25,612	25,612	25,612
Rental payments to others	2,068	4,161	4,394
Rent, communications, and utilities	15,200	17,796	21,465
Printing and reproduction	2,955	3,408	3,812
Contracts and other services	79,447	90,794	121,245
Supplies and materials	17,919	21,015	24,537
Equipment	22,362	26,127	32,262
Grants, subsidies, and contributions	9,991	11,738	12,450
Insurance claims, and indemnities	959	1,136	1,194
Construction	22,500		
Total other objects	212,143	217,122	263,968
Total direct obligations	541,589	576,816	685,172
Unobligated balance lapsing	(63)		

DISTRIBUTION OF RESOURCES

Mr. **Whitten**. Please provide for the record an update of the tables on pages 31 and 32 of your budget justifications to reflect the 1990 column without the $13.0 million supplemental.

Mr. **Benson**. I would be happy to provide that information for the record.

[The information follows:]

DISTRIBUTION OF RESOURCES

[Dollar amounts in thousands]

	1989		1990		1991	
	Amount	FTE	Amount	FTE	Amount	FTE
Foods						
Foodborne biological hazards	50,912	857	61,450	887	85,252	1,112
Molecular biology and natural toxins: Foods and cosmetics	9,327	157	10,442	157	12,005	167
Pesticides and chemical contaminants	30,773	518	36,087	523	44,634	580
Diet/toxicity interaction	4,040	68	4,523	68	5,365	73
Postmarket surveillance and epidemiology: Foods and cosmetics	1,545	26	1,730	26	1,852	26
Technical assistance: Foods and cosmetics	11,525	194	12,903	194	13,811	194
Food and color additive petition review and policy development	12,415	209	13,899	209	14,877	209
Risk assessment research and policy development: Foods and cosmetics	4,693	79	5,254	79	5,624	79
Food composition, standards, labeling, and economics	11,941	201	13,367	201	14,308	201
Cosmetics and color technology	4,040	68	4,523	68	4,841	68
Total foods	141,211	2,377	164,178	2,412	202,569	2,717
Human drugs:						
New drug evaluation	38,621	587	42,994	653	50,353	706
Orphan drugs	6,534	18	8,691	18	9,012	18
Generic drug evaluation	15,988	243	18,190	273	34,713	389
Over-the-counter drug evaluation	3,816	58	3,853	58	4,096	58
Biopharmaceutics	5,329	81	6,013	86	10,456	119
Drug quality assurance	42,372	644	45,186	685	56,803	765
Bioresearch monitoring	8,882	135	9,210	139	9,981	141
Health fraud	2,698	41	3,027	46	3,409	48
Postmarketing surveillance and epidemiology	5,527	84	5,823	88	6,381	90
Prescription drug advertising and labeling	1,448	22	1,462	22	1,554	22
Total human drugs	131,215	1,913	144,449	2,068	186,758	2,356
Biologics:						
Blood and blood products	32,478	362	34,668	385	36,810	395
Viral and rickettsial products	15,880	177	17,938	222	20,429	242
Bacterial and allergenic products	11,036	123	11,551	123	12,473	129
Bioresearch monitoring	1,077	12	1,215	15	1,441	17
Total biologics	60,471	674	65,372	745	71,153	783
Animal drugs and feeds:						
Pre-approval evaluation	10,868	184	12,775	225	13,847	225
Post-approval monitoring	13,584	230	14,281	230	16,833	242
Total animal drugs and feeds	24,452	414	27,056	455	30,680	467
Devices and Radiological Products:						
Monitoring and quality conformance	37,955	611	42,440	633	47,188	651
Product evaluation	21,866	352	23,600	352	26,602	367
Education and assistance	10,126	163	11,264	168	12,177	168
Bioeffects analysis, test and measurement development	8,510	137	9,856	147	11,815	163
Total Development and Radiological Products	78,457	1,263	87,160	1,300	97,782	1,349
National Center for Toxicological Research	25,545	239	26,792	239	27,885	239
Program management	31,430	348	36,197	348	37,981	348
Contingency			1,975			
GSA rent	25,612		25,612		25,612	
Buildings and facilities	23,950		8,350		4,752	
Total	[1] 542,343	7,228	587,141	7,567	685,172	8,259

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[1] Includes $5,500,000 obligated from the Contingency Fund for AIDS-related work (as appropriated to this Fund during 1988). Excludes $63,000 unobligated balance lapsing.

USER FEES

Mr. WHITTEN. Your request for user fees of $157,175,000 is over $57 million more in collections than you proposed for fiscal year 1990, which was subsequently not allowed by Congress. With a more than 50 percent increase projected in user fees, please provide the Committee with the specifics of your user fee proposal in terms of charges, billing and any exemptions provided.

Mr. BENSON. The total projected for 1991 is higher than last year's proposal primarily because of the increased resources needed for our generic drug activities, and also because of the additional proposal for seafood inspection user fees under present law. The seafood fees projected are $5 million, and our expanded generic drug activities are projected to cost $28 million more in 1991 than the base for this program, with all of the increase proposed to be funded via user fees. The base product application review activities for which fees are proposed are estimated at $124 million in 1991, compared to $100 million in the 1990 proposal, because of increased resources devoted to these functions in 1990 as well as increases requested for 1991.

In the special case of generic human drugs, we are proposing an annual monitoring fee for each approved generic drug to support the unusual level of surveillance over this industry which has been found to be necessary. This fee, which we presently estimate at about $6,000, would be collected annually on a specific date.

In the case of seafood inspection, FDA and the National Marine Fisheries Service are in the process of developing an enhanced voluntary seafood inspection program to be conducted jointly by our two agencies. NMFS currently conducts such a program using hourly rates for different types of inspectional activities. The new program will be similar, but based on new principles of industry quality assurance using the Hazard Analysis Critical Control Point concept. The precise fees to be charged under this program have not been set.

For all of the major FDA product application review activities, the fee would be paid with the application, or the agency would not file and review the application. Actual fees would have to be set by regulation depending on the final form of authorizing legislation as passed by Congress. However, at present we would estimate that a Food Additive Petition would have a fee of about $150,000, while a New Drug Application would cost around $400,000. A human generic drug application would have a fee of around $30,000. A New Animal Drug Application fee would be about $130,000, and a new generic animal drug application fee would be about $20,000. For devices, a Premarket Approval application fee would be around $100,000, while a notice of intent to market—known as a 510(k)—would have a fee around $1,000.

These estimated fees assume all of the applications in a category are charged the same fee. The legislative proposal which is being developed would provide for the Secretary to reduce or waive fees in certain instances in the public interest. We expect that this would include exemption for what are known as orphan products, where there is a small market for the product, and perhaps some reduction or exemption for small businesses, although our revenue estimates do not take into account the possibility of any exemptions.

Mr. WHITTEN. For the record, please provide your specific legislation proposed for user fees.

Mr. BENSON. The legislative proposal has not been finalized within the Administration. We will provide the Committee with the proposal as soon as possible.

[CLERK'S NOTE.—Subsequent to the Hearing, the legislative proposal was transmitted to Congress on April 4, 1990. The proposal is included here for the record.]

[The information follows:]

I

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 4 1990

The Honorable Thomas S. Foley
Speaker of the House of
  Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

Enclosed for the consideration of the Congress is a draft bill entitled the "Food, Drug and Device Fee Amendments of 1990". This legislative proposal would implement the President's FY 1991 budget plan.

The draft bill is an expanded version of a draft bill that I transmitted to the 101st Congress on April 3, 1989, which was introduced as H.R. 2482. The bill would require the Secretary of Health and Human Services to assess fees for premarket approval by the Food and Drug Administration (FDA) of food additives, human and animal drugs, antibiotics, medical devices, and biological products, and would permit the Secretary to assess fees for monitoring and testing of marketed products subject to FDA regulation. Fees charged for applications for new drugs, new animal drugs, and medical devices could include costs of review of requests for exemptions with respect to products intended solely for investigational use. The bill does not require fees for investigational use reviews which do not result in an application for marketing approval.

Fees could be set at up to the full amount of all costs to the Federal Government in connection with the activity. Fees for monitoring or testing with respect to categories of marketed products (such as generic drugs or medical devices) could be assessed against all entities subject to regulation with respect to that category. Portions of fees based on FDA's costs would be retained by FDA for use in the same activities; portions based on other costs of the Federal Government would be deposited as miscellaneous receipts of the Treasury. The Congress would determine, through the annual appropriations process, the amount of fees so credited that would be available for current use by FDA.

By authorizing FDA to retain for use in its product review activities portions of fees based on costs incurred by FDA in these activities, the draft bill would provide FDA with the resources to conduct high quality reviews of new product applications as quickly as possible, and thereby enhance its role in bringing safe and effective new products to the American public expeditiously. This authority would also permit financing the costs of review of these products by the producers and manufacturers who benefit directly from such reviews, rather than from general revenues. Similarly, the authority to assess fees for monitoring activities could enable FDA to intensify its oversight of marketed products without increasing the costs to the taxpayer.

The bill would become effective upon enactment, but no fees authorized by the bill would be charged until implementing regulations had been promulgated. The bill also provides for waivers and reductions of fees in exceptional cases in the public interest.

The provisions of the bill are discussed in detail in the enclosed section-by-section summary.

We urge the Congress to give the draft bill its prompt and favorable consideration.

The Office of Management and Budget has advised that enactment of the draft bill would be in accord with the program of the President.

Sincerely,

/s/ Louis W. Sullivan, M.D.

Louis W. Sullivan, M.D.
Secretary

Enclosures

FOOD, DRUG AND DEVICE FEE AMENDMENTS OF 1990

SUMMARY

SHORT TITLE

Section 1 of the draft bill gives its short title. When enacted, it would be cited as the "Food, Drug and Device Fee Amendments of 1990".

REQUIREMENT TO ESTABLISH FEES FOR CERTAIN ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION

Section 2 of the draft bill would amend the Federal Food, Drug, and Cosmetic Act ("the Act") to add a new section 710, entitled "FEES FOR CERTAIN ACTIVITIES".

> Section 710(a) would require the Secretary to assess fees for premarket approval by the Food and Drug Administration (FDA) of food additives, human and animal drugs, antibiotics, medical devices, and biological products, and would permit the Secretary to assess fees for monitoring and testing of marketed products subject to FDA regulation. Fees would be set by regulation, could be set at up to the full amount of all costs to the Federal Government in connection with the activity.
>
> Fees charged for applications for new drugs, new animal drugs, and medical devices could include costs of review of requests for exemptions with respect to products intended solely for investigational use. The bill does not require fees for investigational use reviews which do not result in an application for marketing approval.
>
> Fees with respect to categories of marketed products (such as generic drugs or medical devices) could be assessed against all entities subject to regulation with respect to that category, would be based on the cost of the activity, and could vary to reflect the cost of such activities with respect to different entities or groups of entities.
>
> Subsection (b) would permit regulations under this new authority to make reasonable provision for reduction or waiver of fees in exceptional circumstances, where such waiver or reduction was found to be in the public interest.
>
> Subsection (c) would credit to the FDA appropriations account that portion of collections based on costs incurred by FDA. (That portion of collections based on costs to the Federal Government other than costs to FDA would be deposited as miscellaneous receipts of the Treasury.) Collections credited to FDA would be available without fiscal year limitation, but subject to annual appropriations, for FDA's administrative costs connected

with carrying out the activities for which the fees were collected. Fees collected for each type of activity could be used only for costs connected with carrying out that type of activity.

Subsection (d) would provide that, where the fee for monitoring and testing of an approved product had not been timely received, the fee would be treated as a claim of the United States Government subject to the provisions of title 31, chapter 37, subchapter II of the United States Code.

CONFORMING AMENDMENTS

Section 3 of the draft bill would make conforming amendments to authorities for product approvals by FDA, which would treat the application for such approval as incomplete unless accompanied by the required fee.

A BILL

To require the Secretary of Health and Human Services to impose fees under the Federal Food, Drug, and Cosmetic Act for the review of applications for marketing approval for new human and animal drugs, antibiotics, medical devices, and biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food, Drug and Device Fee Amendments of 1990".

FEES FOR CERTAIN ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION

Sec. 2. The Federal Food, Drug, and Cosmetic Act is amended by adding after section 709 (21 U.S.C. 379a) the following new section:

"FEES FOR CERTAIN ACTIVITIES

"Sec. 710. (a) AUTHORITY TO ESTABLISH AND COLLECT FEES.--The Secretary --

"(1) shall establish by regulation fees, in accordance with the provisions of this section, for reviews conducted by the Secretary of --

"(A) petitions with respect to food additives pursuant to section 409, and petitions for affirmation, pursuant to sections 201(s) and 701(a), that a substance that becomes a component of food is generally recognized as safe;

"(B) applications with respect to new drugs submitted pursuant to section 505(b);

"(C) abbreviated applications with respect to new drugs submitted pursuant to section 505(j);

"(D) applications with respect to antibiotic drugs submitted pursuant to section 507;

"(E) notifications with respect to medical devices submitted pursuant to section 510(k);

"(F) applications with respect to new animal drugs submitted pursuant to section 512(b)(1);

"(G) abbreviated applications with respect to new animal drugs submitted pursuant to section 512(b)(2);

"(H) applications with respect to medical devices (including proposed product development protocols) submitted pursuant to section 515; and

"(I) applications for licensing of biologic products submitted pursuant to section 351 of the Public Health Service Act; and

"(2) may establish fees, pursuant to regulations under this section, for monitoring and testing of any or all marketed products (or groups of products) subject to regulation by the Food and Drug Administration

in amounts up to the full amount which the Secretary reasonably estimates to be sufficient to cover all costs to the Federal Government associated with such activities. Fees established pursuant to paragraph (1) shall include an appropriate share of the estimated average costs incurred pursuant to section 505(i), 512(j), or 520(g). Fees established for a given fiscal year pursuant to paragraph (2) may be charged to all entities (or all members of a group of entities) which market during the fiscal year products subject to the monitoring and testing activities for which the fee is charged. The amount of fees established pursuant to paragraph (2) may vary to reflect the cost of such activities with respect to different entities or groups of entities, including the type and size of entity, volume of business, and such other factors as the Secretary may find appropriate.

"(b) REDUCTION OR WAIVER OF FEES.--Regulations establishing fees pursuant to this section may make reasonable provision for reduction or waiver of fees in exceptional circumstances in the public interest.

"(c) CREDITING AND AVAILABILITY OF FEES.--(1) Fees collected pursuant to this section which are based on costs incurred by the Food and Drug Administration shall be credited to the appropriation account for the Food and Drug Administration, and shall be available, without fiscal year limitation and in the amounts provided in appropriations acts, for salaries and expenses necessary to carry out the responsibilities of the Food and Drug Administration in connection with activities specified in subsection (a), including the conduct of scientific research; development of methods of analysis; purchase of chemicals, fixtures, furniture, and scientific equipment and apparatus;

acquisition, maintenance, and repair of real property; and expenses of advisory committees. Fees collected for each category of activities specified in subsection (a) shall be separately accounted for, and shall be used only to finance the costs related to carrying out responsibilities in connection with the same category of activities for which such fees were collected.

"(2) Fees collected which are based on costs of the Federal Government other than costs incurred by the Food and Drug Administration shall be credited to the Miscellaneous Receipts Account of the Treasury General Fund.

"(d) COLLECTION OF UNPAID FEES.--(1) In any case where the Secretary does not receive payment of a fee assessed under subsection (a)(2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to the provisions of title 31, chapter 37, subchapter II of the United States Code.".

CONFORMING AMENDMENTS

Sec. 3. (a) FOOD ADDITIVE PETITIONS.--(1) Section 409(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(2)) is amended by adding at the end the following new sentence: "The petition shall be accompanied by any fee required by regulation pursuant to section 710.".

(b) NEW DRUG APPLICATIONS.--Section 505(b)(1) of that Act (21 U.S.C. 355(b)(1)) is amended by adding at the end the following new sentence: "The application shall be accompanied by any fee required by regulation pursuant to section 710.".

(c) ABBREVIATED NEW DRUG APPLICATIONS.--Section 505(j)(2)(A) of that Act (21 U.S.C. 355(j)(2)(A)) is amended by adding at the end the following new sentence: "The application shall be accompanied by any fee required by regulation pursuant to section 710.".

(d) ANTIBIOTIC DRUG APPLICATIONS.--Section 507(a) of that Act (21 U.S.C. 357(a)) is amended by adding at the end the following new sentence: "The application shall be accompanied by any fee required by regulation pursuant to section 710.".

(e) MEDICAL DEVICE NOTIFICATIONS.--Section 510(k) of that Act (21 U.S.C. 360(k)) is amended by adding at the end the following new sentence: "The notification shall be accompanied by any fee required by regulation pursuant to section 710.".

(f) NEW ANIMAL DRUG APPLICATIONS.--Section 512(b)(1) of that Act (21 U.S.C. 360b(b)(1)) is amended by adding at the end the following new sentence: "The application shall be accompanied by any fee required by regulation pursuant to section 710.".

(g) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.--Section 512(b)(2) of that Act (21 U.S.C. 360b(b)(2)) is amended by adding at the end the following new sentence: "The application shall be accompanied by any fee required by regulation pursuant to section 710.".

(h)(1) MEDICAL DEVICE APPLICATIONS.--Section 515(c)(1) of that Act (21 U.S.C. 360e(c)(1)) is amended --

(A) in subparagraph (G), by striking out the period at the end and inserting a comma instead; and

(B) by adding below and two ems to the left of subparagraph (G) "and shall be accompanied by any fee required by regulation pursuant to section 710.".

(2) Section 515(f)(2) of that Act (21 U.S.C. 360e(f)(2)) is amended by adding at the end the following new sentence: "In order to be complete, such protocol shall be accompanied by any fee required by regulation pursuant to section 710.".

(i) APPLICATIONS WITH RESPECT TO BIOLOGICAL PRODUCTS.--Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended by adding at the end the following new sentence: "Each application for a license under this section shall be accompanied by any fee required by regulation pursuant to section 710 of the Federal Food, Drug, and Cosmetic Act.".

FDA'S 1991 BUDGET REQUESTS

Mr. **Whitten**. What was FDA's budget request to the Public Health Service, the Public Health Service's request to the Department of Health and Human Services and their request to OMB? Also show the final request made to Congress. Also note with that table the point at which user fees were inserted into the budget request and in what amounts.

Mr. **Benson**. I would be happy to provide that information for the record

[The information follows:]

HISTORY OF FDA'S 1991 BUDGET REQUESTS

[In thousands of dollars]

	Request to—			
	PHS	DHHS	OMB	Congress
Salaries and expenses	787,176	688,250	657,350	654,808
Buildings and facilities	26,450	21,450	13,450	4,752
Rent to GSA	40,765	40,765	25,612	25,612
Total	854,391	750,465	696,412	685,172
User fees proposed as part of total	16,075	16,075	144,175	157,175

DELANEY CLAUSE

Mr. **Whitten**. Please describe for us any lawsuits or activity related to your application of the Delaney Clause. Last year you pointed out several instances of lawsuits. Have they been terminated?

Mr. **Benson**. Last year, Dr. Young described four lawsuits challenging FDA's regulation of certain food and color additives under the Delaney Clause. All four of those suits were completed at the time of that response. Since that time, there has been one lawsuit filed against FDA concerning the Delaney Clause; in addition, the agency has taken regulatory action against one color additive on the basis of the Delaney Clause.

Last September, Public Citizen Health Research Group sued FDA, challenging the agency's regulation of the color additive FD&C Red No. 3. In that suit, Public Citizen alleged that FD&C Red No. 3 is an animal carcinogen and that FDA had unreasonably delayed termination of the provisionally listed uses as well as revocation of the permanently listed uses. At that time, FD&C Red No. 3 was provisionally listed for use in externally applied drugs and cosmetics; all uses of the lake form of the color additive were also provisionally listed. The color additive is also permanently listed for use in food and ingested drugs.

The Public citizen lawsuit was subsequently settled by a stipulation of voluntary dismissal following FDA's publication in the February 1, 1990, Federal Register of a final rule terminating the provisionally listed uses of FD&C Red No. 3. At the same time, FDA published a notice denying the petition of the Cosmetic, Toiletry, and Fragrance Association for permanent listing of FD&C Red No. 3 for cosmetic and externally applied drug uses. FDA took these actions because chronic toxicity studies of the color additive conducted in rodents established that it is an animal carcinogen. Specifically, male rats fed FD&C Red No. 3 at the 4 percent dose level developed thyroid tumors. The proponents of FD&C Red No. 3 contended that the available scientific data demonstrated that the color additive exerted its tumorigenic effect through a secondary mechanism and that such secondary carcinogens were exempt from the proscription of the Delaney Clause. FDA determined, however, that the data submitted by the proponents did not establish the operation of the secondary mechanism. Therefore, because FD&C Red No. 3 had been shown to be an animal carcinogen, FDA concluded that the Delaney Clause compelled the agency to deny the pending CTFA petition and to terminate the provisional listings for the color additive.

The Food, Drug, and Cosmetic Act provides the proponents of FD&C Red No. 3 with mechanisms for review of FDA's petition denial. On March 5, 1990, CTFA and the Certified Color Manufacturers' Association each filed a citizen petition with FDA, requesting that the secondary mechanism issue be referred to a Color Additives Advisory Committee. The agency is currently reviewing the CTFA and CCMA citizen petitions.

AIDS ACTIVITIES

Mr. WHITTEN. Please provide a table showing fiscal years 1989, 1990 and 1991 AIDS-related activities. Break that table down into the amounts for biologics, drugs, and any other categories.

Mr. BENSON. Certainly. I will be glad to do so.

[The information follows:]

FDA AIDS ACTIVITIES, 1989–91

[In thousands of dollars]

	1989	1990	1991
Drugs	17,005	19,181	22,615
Biologics	26,595	28,375	31,254
Devices	7,675	8,664	9,367
New Building	22,500	0	0
Total FDA	73,775	56,220	63,236

APPROVED AIDS DRUGS

Mr. WHITTEN. Please provide a listing of all the drugs that have been approved for AIDS applications. How long did it take from the time of request for approval by a pharmaceutical manufacturer until final approval was received from FDA to market the product?

Mr. BENSON. I would be pleased to provide that information.

[The information follows:]

THERAPIES APPROVED FOR AIDS

Product	Date approval		Time interval (months)
	Requested	Granted	
Antiretroviral Drugs: Retrovir, Zidovudine (AZT)—			
Capsules	Dec. 2, 1986	Mar. 19, 1987	3.5
Syrup	Oct. 28, 1988	Sept. 28 1989	11
Injection	Feb. 1, 1989	Feb. 2, 1990	12
Drugs/Biologics for AIDS-Associated Conditions:			
Cytovene, Ganciclovir	Dec. 29, 1986	June 23, 1989 [1]	25
Diflucan, Flucanozole			
Tablets	Mar. 2, 1989	Jan. 29, 1990	11
Injection	Nov. 21, 1989	do	10
Interferons, Alpha a and Alpha b (biologic products)	Sept. 30, 1983	Nov. 21, 1988	61
Nebupent, Pentamidine			
Injection	Apr. 1, 1984	Oct. 1, 1984	6
Aerosol	July 29, 1988	June 15, 1989	11

[1] NDA withdrawn Nov. 23, 1988 and resubmitted May 1, 1989

AIDS-RELATED INSTITUTIONAL CHANGES AT FDA

Mr. WHITTEN. Early in fiscal year 1989 there were two new divisions established in an effort to expedite the AIDS product approval process. The Division of Cytokine Biology and the Division of antiviral Drug Products. In the past year, have there been any significant institutional changes to the Food and Drug Administration to assist in expediting AIDS-related activities?

Mr. BENSON. There have been no major organizational changes in the past year, but a number of initiatives are ongoing to expedite product development and study.

Many of the ongoing trials with both drugs and biologics are now listed in the AIDS Clinical Trials Information Service—ACTIS. On July 18, 1989, FDA joined CDC and NIH in publicly releasing information about AIDS-related clinical trials through the ACTIS toll-free telephone service. More than 80 protocoals are now listed through FDA. We hope that early release of information through the database may result in a much wider patient population from which to draw during clinical trials enrollment.

In addition to efforts such as expedited review and the Treatment IND process, we are working to design and implement a "parallel track" mechanism whereby promising investigational drugs and biologics can be made available at an early point in the drug development process to people who have no satisfactory alternative therapy, or who are failing on available therapy, and who cannot qualify for or otherwise participate in ongoing controlled clinical trials. Documents related to this mechanism, both regulatory and procedural, are scheduled for publication soon.

1-AA DRUGS

Mr. WHITTEN. Of all the 1-AA designated drugs, how many have been approved to date?

Mr. BENSON. To date, four drugs which were designated 1-AA have been approved. These are Zidovudine, Ganciclovir, Flucanozole, and Pentamidine. One New Drug Application designated 1-AA is currently under review.

Mr. **Whitten**. Please bring us up to date on the status of the number of drugs that have been given the 1-AA designations.

Mr. **Benson**. Currently, there are 160 Investigational New Drug applications with 1-AA designations which have been approved for clinical study.

AFLATOXIN

Mr. **Whitten**. With drought affecting much of the Nation the past years, there was significant discussion last year about aflatoxin in the public food chain. FDA's action level for aflatoxin in human food is 20 parts per billion. In this past year have there been any instances where FDA has found the action level has been exceeded and what were the circumstances surrounding those?

Mr. **Benson**. In FY89, FDA analyzed 87 samples of sweet corn, none of which exceeded the 20 ppb action level. Similarly, none of the 176 samples of manufactured corn-based products we analyzed, such as snack and breakfast foods, exceeded the 20 ppb level, nor did the 30 lots of popcorn we sampled and analyzed for aflatoxins. We did find that one of 653 samples of milled corn products, for example, meal, flour, grits, contained more than 20 ppb aflatoxins. The sample, however, had apparently been damaged during shipment in that it was wet when it arrived at our Atlanta laboratory. The subject lot was unavailable for resampling. FDA also sampled 2,395 shipments of whole corn. Some of this corn goes to milling and further processing into human food products. Some of it goes to animal feed. One hundred thirty-three of these samples contained in excess of 20 ppb. Whole corn found to contain in excess of 20 ppb, but less than 300 ppb, may be fed to certain non-lactating food-producing animals in accordance with FDA's aflatoxin policy and action levels, because such corn does not present any significant risk to the animals or to people who eat meat derived from those animals.

INFECTIOUS DISEASES SOCIETY OF AMERICA

Mr. **Whitten**. In June 1988 the Food and Drug Administration issued a contract with the Infectious Diseases Society of America to update existing guidelines in the field of infectious diseases and antimicrobial therapies. What is the status of this contract and, to date, can you give us an idea of some of the recommendations to be made?

Mr. **Benson**. To date, 13 committees have generated over 400 pages of draft proposals and we estimate that IDSA should be completing their guideline recommendations by November of this year. Upon FDA review and concurrence, these recommendations will be published in a prominent medical journal. Finally, FDA will consider these recommendations for inclusion as regulatory documents to be published as formal guidelines for the clinical study of anti-infective drug products.

APPROACHES TO RECRUITMENT

Mr. **Whitten**. Over the years, one of the criticisms that people have made concerning the FDA is its inability to hire or recruit reviewers, particularly medical officers, for its highly technical work.

Last year Dr. Young testified that in conjunction with the Pharmaceutical Manufacturers Association, you were studying innovative approaches to recruitment. What were the recommendations provided by the Task Force that looked into the issue?

Mr. BENSON. In summary, the joint FDA/PMA Task Force for the improvement of the recruitment of Medical Reviewers in the Center for Drug Evaluation and Research made seven recommendations. These were to develop and maintain an ongoing, organized and centralized recruitment process for medical reviewers, which can be individualized to meet specific staffing needs; identify and develop a multitude of sourcing strategies; actively manage the internal recruitment process; improve the interview process; strengthen management of the job offer; appoint a dedicated, full-time Medical Reviewer recruitment manager; and, develop a long-term public relations campaign to improve FDA's image in the medical community.

The starting point for the realization of these recommendations was the appointment of a dedicated recruitment manager. This occurred in June, 1988, and the recruitment manager then developed a comprehensive recruitment guide which incorporated the first five recommendations. The guide was implemented in July, 1988.

Specifically, the recruitment manager now serves as the focal point, for both managers and applicants, for an ongoing and organized recruitment process for Medical Reviewers.

The interview process has been standardized to include both division-level and higher level officials and the recruitment manager. This allows the hiring decision to be made in a relatively short time, usually seven to ten days, after the interview is completed.

We continue to promote FDA employment opportunities at conferences and scientific meetings and other public occasions. The result has been that individuals with very strong credentials who might not have considered the agency previously are coming now to discuss opportunities. It is encouraging to see that an increasing number of individuals are considering FDA as a career possibility.

RECRUITMENT REPORT

Mr. WHITTEN. The Conference Report accompanying the Food and Drug Administration's Appropriations Bill for fiscal year 1989 requested that FDA provide a report to the Committee on the difficulties it was having in recruiting medical officers and other scientists. This report was requested before January 15, 1989. When do you expect to provide the report to the Committee?

Mr. BENSON. We are just completing our second version of this report, in response to criticism that the documentation included in the initial draft report was inadequate to support the position in the report. We therefore made it our objective to make sure our data is as comprehensive as possible and have worked with PHS and Departmental staff in thorough analyses of the recruitment and retention data. The report is now being reviewed within the Department and we expect it to be transmitted very soon.

SALMONELLA IN EGGS

Mr. **Whitten.** For the record, what resources have you expended related to solving and tracking the problem related to *Salmonella enteritidis* in eggs?

Mr. **Benson.** The Division of Microbiology, Center for Food Safety and Applied Nutrition, has analyzed feed and chicken internal organs for the presence of *Salmonella enteritidis.* In addition, the Division has developed a Polymerase Chain Reaction method that can detect low levels of this organism in either feeds, chicken internal organs, or environmental samples. Heat studies, to determine the efficiency of egg pasteurization to destroy this organism, were also performed as well as research to study the growth kinetics of this microbe in whole eggs and egg yolk. Our Baltimore field laboratory has examined environmental samples for the presence of this microbe. It is estimated that a total of eight staff years have been devoted to research on this microbe or analyses of samples since April, 1988.

It is also estimated that at least three staff years have been devoted to administrative meetings with USDA, briefings for FDA personnel, and talks given to outside organizations. Field investigational activities, epidemiological tracebacks, diversion to pasteurization, and other relayed activities, have consumed an estimated two staff years. FDA has also provided one person to CDC for the past two years to aid them in their bacteriophage typing of isolates. Finally, FDA has employed one individual in the drafting of Regulations to cover this problem.

Overall, we estimate that FDA has devoted 16 staff years to this problem since April, 1988.

Mr. **Whitten.** In February of this year the Department of Agriculture announced emergency transfer of funds from the Commodity Credit Corporation to its Animal and Plant Health Inspection Service to begin a mandatory testing procedure for *Salmonella enteritidis.* Now that USDA has entered itself into solving the salmonella problem with much more resources than it had previously, will FDA be able to reduce its effort in the area?

Mr. **Benson.** FDA will continue to provide a staff year to CDC for the performance of bacteriophage typing, will continue epidemiological tracebacks and the monitoring of egg diversions to pasteurizers, and will provide analytical assistance as needed. It is estimated that at least six FTEs will be devoted to this problem in this fiscal year. For 1991, FDA is requesting an increase of 20 FTEs to expand applied research including development of improved test methods for pathogenic bacteria.

IMPORTED FOOD

Mr. **Whitten.** The numbers of imported food items coming into this country continues to increase significantly over the years. The ability of the FDA to keep up with imports is significantly strained considering all of its other activities. Last year, Dr. Young briefed us on the concept of the Import Support and Information System, known as ISIS. He indicated that the FDA had requested procurement authority from the Department of Health and Human Services for a five-year program ending in 1993 to implement the ISIS project. Have you received authority from DHHS and have you begun any procurement?

Mr. **Benson**. FDA has received authority for a five-year contract to procure hardware, software and personal computers for support of the Office of Regulatory Affairs Field Information System of which ISIS is a major component. Procurement efforts for a competitive contract are under way and plans include the purchase of necessary hardware, software and maintenance support following the ISIS pilot test. The pilot test is anticipated to begin this summer.

Mr. **Whitten**. What is the total cost projected for this system on an annual basis?

Mr. **Benson**. The estimated resources to maintain the ORA Field Information System including ISIS are estimated to be $3,000,000 per year. This estimate covers hardware and software maintenance, estimated telecommunications service and computer support personnel. It is anticipated that additional costs will be incurred to expand and enhance the ISIS system over the next several years. These costs will be estimated following the implementation of the system and an appropriate evaluation period.

FIELD STAFFING

Mr. **Whitten**. Throughout your budget justifications there are increases to restore FDA's field capabilities. For the record, please provide a table showing each Center's request related to restoration of field capability. Also provide a column comparing FDA's resources in fiscal year 1980 for field capability. In your table, for each Center's request, break out the amount proposed for salaries and expenses related to FTEs and the amount to replace or purchase new scientific equipment.

Mr. **Benson**. I would be happy to provide that information for the record.

[The information follows:]

FDA's FIELD STAFFING

[Dollar amounts in thousands]

	Fiscal years, 1980-90					1991 increases to support	
	FTE	Amount	FTE	Amount	FTE	FTE's	Equipment
Foods	1,390	$45,191	1,475	$100,398	75	$5,625	$975
Human drugs	984	28,978	792	56,973	25	1,875	500
Biologics	144	4,487	139	12,196			
Animal drugs/feeds	157	5,770	149	8,860	12	900	500
Devices and rad health	562	16,642	361	24,203	13	975	500
Other	71	2,338	49	5,096			
Total	3,308	103,406	2,965	207,726	125	9,375	2,475

FORENSIC LABORATORY

Mr. **Whitten**. Last year's scare concerning cyanide in Chilean grapes caused the FDA to redirect hundreds of man-hours of its resources. It has been reported that one of the main shortcomings of

FDA's ability to look into the cyanide issue was the lack of a mobile forensic chemistry laboratory owned by FDA. Has FDA done anything since then to purchase such a laboratory?

Mr. BENSON. It is true that FDA redirected a number of resources during the Chilean fruit crisis for inspectional purposes but it is our belief that all laboratory analyses were performed expeditiously and effectively. A mobile laboratory devoted solely to perform cyanide analyses would have been too costly and counterproductive. A forensic chemistry mobile laboratory would be impractical for the Agency to have because of the multitude of equipment that would be necessary and the special requirements needed to operate the instruments. What the agency needs is a stationary forensic laboratory to conduct research on various kinds of poisons and how they react in various FDA regulated products. That is what we are seeking resources for in our 1991 budget request.

FDA has established a forensic chemistry laboratory in Cincinnati and the equipment cost alone is in the vicinity of $1.7 million.

SEAFOOD USER FEES

Mr. WHITTEN. You propose an increase of over $14 million to expand the surveillance of seafood products and related activities. You have indicated that $5 million of this would result through voluntary fees under present statutory authority. Please submit a copy of that specific authority. Does it allow the FDA to retain these fees or are they deposited back into the general Treasury?

Mr. BENSON. Section 702A of the Federal Food, Drug, and Cosmetic Act, as amended, provides discretionary authority to the Secretary, and by delegation, the Commissioner, to establish a seafood inspection program. The program may provide for the use of a mark on the product to show that that product has been produced under the program. In fact, FDA formerly conducted inspections under this authority, but the program was discontinued in the late 1950's. At present, FDA inspects seafood under the authority of the FD&C Act, and the National Marine Fisheries Service operates a fee-for-service inspection program for those firms requesting it, and the two agencies coordinate their activities under a Memorandum of Understanding.

The two agencies are proposing a new, enhanced program under this authority which will involve the expertise of both agencies and will require industry to use the Hazard Analysis Critical Control Point concept of assuring product safety and quality. Section 702A specifically provides for the fees to be available for the cost of carrying out the program. This would be similar to our certification program for color additives and insulin, in which industry fees are deposited in the Treasury in a separate account on which FDA draws to pay the costs of the program.

I would be happy to provide for the record a copy of this section of law.

[The information follows:]

SEAFOOD INSPECTION

SEC. 702A. The Secretary of Health and Human Services, upon application of any packer of any seafood for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Health and Human Services for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is hereby authorized to promulgate regulations governing the sanitary and other conditions which the services herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000 or both such imprisonment and fine.

SEAFOOD USER FEE PROGRAM

Mr. WHITTEN. Please provide the analysis that was done to determine that $5 million could be collected from industry.

Mr. BENSON. The present voluntary seafood inspection program operated by the National Marine Fisheries Service covers about 10% of the seafood packed in this country. Because there has been substantial attention drawn to the safety of seafood in recent times, we believe the industry is interested in assuring the public about the safety of its products. In addition, we believe that industry will be increasingly interested in a program that provides a specific mark that evidences that the firm participates in the new program because that mark will be considered desirable when seeking to sell products to government agencies, other institutions, and foreign countries, in addition to American consumers.

The precise fees for this program have not yet been set. The estimate of $5 million for 1991 is simply an estimate of the level of services that FDA, in conjunction with NMFS, will be able to provide, and it assumes industry applies for the program.

Mr. WHITTEN. For the record, please submit the proposed rules under which the voluntary program would be operated.

Mr. BENSON. We have not yet published the rules for this program, since we are working out the details with the National Marine Fisheries Service. We expect an advance notice of proposed rulemaking to be published in the near future, however.

SEAFOOD ILLNESSES

Mr. WHITTEN. Your budget justifications point out that the agency has serious concerns over current seafood health and safety issues. Yet, in previous testimony from FDA officials to other Committees they have pointed out that health related concerns related to red meat and poultry are significantly more than that of seafood. For the record, please provide a five-year table showing the outbreaks of serious illnesses from food related poisonings for red meat, poultry, seafood and shellfish. If the data is available, also show the pounds consumed for each of these products.

Mr. BENSON. There are two primary sources of data on the comparative safety of seafood versus terrestrial sources of muscle protein, first, the passive reporting system of the Centers for Disease Control that records those outbreaks of foodborne illness reported to it by local health authorities, and second, FDA's risk assessment estimate of all individual illness from seafood and chicken that actually occur in the U.S. in a single year, not just those reported to CDC. This risk assessment estimate is primarily an attempt to correct for both the underreporting of foodborne illness to CDC generally and the differences that can occur in rates of underreporting for different foods, for example, seafood versus chicken. Differences in the rates of underreporting can cause a food that is riskier than another to appear to be safer, and vice versa, when the raw data that has been reported to CDC for both foods are compared.

FDA's risk assessment uses estimates in the published literature and from various case studies to augment the CDC data. CDC reviewed this risk assessment estimate and advised FDA that it is consistent with CDC's experience in studying and tracking foodborne illness. The testimony of FDA officials to other committees about the comparative safety of seafood has been based largely on the risk assessment findings.

It is not difficult to see how outbreaks can be reported to CDC at different rates for different foods. For example, ciguatera illness from finfish has a rapid onset and characteristic symptoms that lead to the high probability that this illness will be correctly diagnosed and will also be reported; however, the leading causes of foodborne illnesses, the bacteria Salmonella and Campylobacter, are less easily associated with the specific meal eaten, and the resulting illnesses are less likely to be reported by the victim. These two genra of bacteria are commonly associated with meat and poultry but seldom with any of the many species and forms of seafood.

Another phenomenon that causes seafood and terrestrial sources of muscle protein to be reported at different rates is the reporting of individual illnesses that are clearly related to seafood into CDC's outbreak reporting system. Again, an outbreak is defined as involving two or more illnesses from a single source. The entry of single illnesses for terrestrial sources of muscle protein into CDC's outbreak reporting system is not known to occur.

As a further complicating factor, numbers of outbreaks may bear little relationship to the numbers of individual illness that occur because the number of illnesses per outbreak may vary considerably among different foods. This problem can be compensated for, in part, by counting the number of illnesses in the outbreaks and then arranging the data as individual illnesses instead of outbreaks. FDA's risk assessment estimate does present its results in terms of individual illnesses. I would be pleased to provide more detail for the record.

[The information follows:]

The data reported to CDC and the data from FDA's risk assessment estimate are presented below. This data was compiled by FDA for the 15-year period 1973-1987 prior to Congressional hearings on seafood. Separate year-by-year data is not readily available. First, are the total amounts of these foods consumed for a fifteen year period; second, are the data that have been reported to CDC's passive system; third, are the data as corrected by FDA's risk assessment estimate.

1. Total amounts eaten in 1973-1987 in billions of pounds from USDA data:

Beef	265.2
Pork	148.2

Chicken	118.6
Turkey	28.7
Shellfish	12.0
Fish	34.0
Total Seafood	46.0

2. The data as reported to CDC's passive reporting system:

(a) Total number of outbreaks of serious illnesses. [Note: as discussed below in item 3, these data are for all reported illnesses.]

Number of outbreaks reported to CDC 1973-1987:

Beef	327
Pork	252
Chicken	120
Turkey	133
Shellfish	213
Fish	540

(b) In order to compare these data, the following tables present the average yearly number of outbreaks reported to CDC and the average yearly number of individual illnesses associated with the outbreaks normalized to billions of pounds consumed per year for the period 1973-1987:

CDC data on outbreaks reported to its passive system on a per lbs. consumed basis:

All seafood—16.7 outbreaks per billion lbs. consumed.

All seafood minus raw molluscan shellfish—15.7 outbreaks per billion lbs. consumed.

Raw molluscan shellfish—17.8 outbreaks per billion lbs. consumed.

Chicken—1.0 outbreaks per billion lbs. consumed.

Turkey—4.7 outbreaks per billion lbs. consumed.

Beef—1.2 outbreaks per billion lbs. consumed.

CDC data from passive system broken down as *individual illnesses* on a *per lbs. consumed* basis:

All seafood—178 illnesses per billion lbs. consumed.

All seafood minus raw molluscan shellfish—98 illnesses per billion lbs. consumed.

Raw molluscan shellfish—388 illnesses per billion lbs. consumed.

Chicken—46 illnesses per billion lbs. consumed.

Turkey—330 illnesses per billion lbs. consumed.

Beef—59 illnesses per billion lbs. consumed.

3. Finally, FDA's risk assessment estimate for all illnesses that occur in a year in the U.S. for seafood and chicken. The estimate is on both a per-pound-consumed and a per-serving basis. The correction provided by the risk assessment estimate causes the relative safety of chicken and seafood to shift substantially from the way it appears to be as reported to CDC's passive system (although the risk assessment still shows that the risk from eating uncooked molluscan shellfish is much higher than for chicken or for all other seafood.) The principal source of illness resulting from the consumption of raw molluscan shellfish is viral gastroenteritis. This is regarded as a mild illness when compared with illnesses from *Salmonella* or *Campylobacter*.

FDA's risk assessment on a *per lbs. consumed* basis:

All seafood—17,000 illnesses per billion lbs. consumed.

All seafood minus raw molluscan shellfish—900 illnesses per billion lbs. consumed.

Raw molluscan shellfish—16.6 million illnesses per billion lbs. consumed.

Chicken—170,000 illnesses per billion lbs. consumed.

FDA's risk assessment on a *per serving* basis:

All seafood—1 illness per 250,000 servings.

All seafood minus raw molluscan shellfish—1 illness per 5 million servings.

Raw molluscan shellfish—1 illness per 250 servings.

Chicken—1 illness per 250,000 servings.

SHELLFISH

Mr. WHITTEN. FDA officials have indicated that a much more serious problem related to the seafood industry has to do with the shellfish industry. FDA's compliance efforts related to domestic raw oysters is carried out in cooperation with the Interstate Shellfish Sanitation Conference. The problems in shellfish appear to be mostly related to polluted waters. What sanctions can the Interstate Shellfish Sanitation Conference place on specific polluted waters, both inside and outside the three-mile interstate limits?

Mr. **Benson**. The National Shellfish Sanitation Program [NSSP] is administered by FDA and provides for the sanitary production of not only raw oysters, but all fresh and frozen molluscan shellfish such as oysters, clams and mussels. Participants include the 23 coastal shellfish producing states, and nine foreign countries.

The Interstate Shellfish Sanitation Conference [ISSC] is an organization of state shellfish control officials, representatives of the shellfish industry, and Federal agencies. The purpose of the ISSC is to provide a formal structure wherein the state regulatory authorities can establish updated guidelines for the sanitary control of the shellfish industry. In this way the ISSC serves as the primary channel for collecting public comment, developing proposals for change, and improving the NSSP.

The present focus of the NSSP and ISSC is not on condemning polluted waters, but rather placing sanctions on products that do not originate from waters certified as being safe. This is a subtle but distinct difference.

The NSSP requires that waters be proven safe before harvesting is allowed. Proper classification of shellfish growing waters is both time consuming and costly. Evaluations of area suitability for harvesting include shoreline surveys to identify and evaluate sources of pollution; routine microbiological testing of water quality; and hydrographic studies to determine the path of pollutants relative to harvestable shellfish resources. All of these components must be evaluated in a written sanitary survey report which describes how the area will be managed for safe shellfish harvesting.

Harvesting prohibitions can therefore result from determining that areas are polluted or are unsafe because of paralytic shellfish poisons or other natural toxins, or the lack of adequate data and written surveys to prove the area is safe for harvesting.

Present sanctions rely mostly on the state's own requirements. These requirements are based not only on the NSSP but on the Retail Food Store Sanitation and Model Food Service Sanitation Codes, which require that shellfish products be from a certified source or origin. Proof of origin is dealer listing in the Interstate Certified Shellfish Shippers List. Products can be rejected in 40 of 50 states if they don't originate from a dealer listed in the ICSSL. Additional rejections may occur based on quality/safety monitoring by receiving states.

Federal law does not require that molluscan shellfish products be from a certified source of origin as demonstrated by listing in the ICSSL. For FDA to take action against a product, it must have evidence of adulteration.

Mr. **Whitten**. Can products harvested in state waters be sold within that state and not be subject to the Interstate Shellfish Sanitation Conference guidelines?

Mr. **Benson**. Yes. The National Shellfish Sanitation Program is specifically designed for the sanitary control of molluscan shellfish in interstate commerce. However, for the sake of program uniformity, the states themselves require that NSSP sanitation controls to be applied uniformly whether the product is for intra or interstate commerce. These safety controls cannot be effectively enforced without the collective support of all state health officials. Delisting shippers from the Interstate Certified Shellfish Shippers List is only effective if receiving states refuse to allow entry of noncertified products. To date, 40 of 50 states have such refusal authority under provisions of state adopted Retail Food Store Sanitation and Model Food Service Sanitation Codes.

Mr. WHITTEN. The FDA signs Memoranda of Understanding—MOU—with foreign governments that meet the National Shellfish Sanitation Program guidelines. How many MOUs have been signed with foreign governments and what precautions does FDA make to assure that foreign governments are abiding by the guidelines?

Mr. BENSON. Nine countries currently have shellfish MOUs with the U.S. Five countries are actively exporting shellfish. Those countries are Australia, Canada, Korea, New Zealand, and Chile. Four countries, England, Mexico, Iceland and Japan, have developed MOUs but are not shipping shellfish.

The MOUs provide for FDA program evaluations like those conducted for domestic shellfish producing states. These evaluations include field visits by FDA personnel to the foreign nation's growing waters, packing plants and laboratory facilities. To obtain and maintain an MOU, the country must demonstrate that its laws, regulations, and procedures covering growing water classification, harvesting, processing, and transporting shellfish products are in compliance with the NSSP Manual of Operations. Additionally, the foreign government must have the trained personnel, laboratory facilities, and other resources necessary to control its shellfish export industry. The nation's public health officials must also complete and maintain sanitary survey reports and inspection reports. In summary, the foreign country must operate and maintain a shellfish sanitation program comparable to those operated in the U.S.

Evaluations are made annually until the program is well established, then evaluations are done biennially.

CONSULTING AND RELATED SERVICES

Mr. WHITTEN. Please provide a list of all contracts for consulting services for fiscal years 1989 and 1990 to date.

Mr. BENSON. I will provide a list for the record. [The information follows:]

[Dollars in Thousands]

Fiscal year 1989:	
Guidelines for testing drugs in children	$42
Analysis and review of topic in nutrition and health	150
Review and evaluation key pediatrics problems	55
Statistical support for the Center for Foods	30
Feasibility study and master plan for national biotechnology cooperative	500
Development of quality assurance program for hemodialysis facilities	88
Evaluation of contact lens labeling for wearers of soft contact lenses	65
Development of the 16th edition of standard methods for the examination of dairy products	34
Total	964

Fiscal year 1990 to date:

Clinical trials—Training	200
THA and Lecithin in Alzheimers disease patients	240
Software safety training	60
Total	500

ADVISORY COMMITTEES

Mr. WHITTEN. Please provide a list of all advisory committees and the associated costs for each for year 1989. Are there any new advisory committees contemplated for fiscal years 1990 and 1991?

Mr. BENSON. I would be pleased to provide that for the record. However, I would note that the number of meetings of many of these committees depends on whether we need to call them into session. Therefore, our 1990 actual expenses may vary from the estimates, depending on whether some committees meet more or less often than planned. One new advisory committee is being contemplated for fiscal year 1990 and no new advisory committees are being contemplated for fiscal year 1991. In addition to the Committees listed, the FDA Advisory Committee has been appointed by the Secretary to advise the Assistant Secretary for Health and the Secretary about a variety of FDA organizational, management, and resource issues.

[The information follows:]

	1989 actual	1990 estimated
Office of the Commissioner: Board of tea experts	$6,800	$6,800
Human Drugs and Biologics:		
Allergenic Products Advisory Committee	0	34,755
Anesthetic and Life Support Drugs Advisory Committee	34,011	57,734
Anti-Infective Drugs Advisory Committee	62,929	57,641
Anti-Viral Drugs Advisory Committee	0	61,935
Arthritis Advisory Committee	33,931	54,454
Biological Response Modifiers Advisory Committee	0	70,149
Blood Products Advisory Committee	68,629	92,541
Cardiovascular and Renal Drugs Advisory Committee	55,826	69,498
Dermatologic Drugs Advisory Committee	28,720	42,084
Drug Abuse Advisory Committee	35,704	54,591
Endocrinologic & Metabolic Drugs Advisory Committee	39,252	54,187
Fertility & Maternal Health Drugs Advisory Committee	65,331	70,710
Gastrointestinal Drugs Advisory Committee	36,376	48,368
Oncologic Drugs Advisory Committee	39,736	48,804
Peripheral & Central Nervous System Drugs Advisory Committee	54,670	71,028
Psychopharmacologic Drugs Advisory Committee	42,907	51,297
Pulmonary-Allergy Drugs Advisory Committee	51,252	58,384
Radiopharmaceutical Drugs Advisory Committee	25,915	40,004
Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee)	0	[1] 38,739
Vaccines and Related Biological Products Advisory Committee	79,363	97,999
Devices and Radiological Health:		
Anesthesiology and Respiratory Therapy Devices Panel	19,862	30,032
Circulatory System Devices Panel	59,867	51,576
Clinical Chemistry & Clinical Toxicology Devices Panel	31,694	46,009
Dental Devices Panel	41,007	47,987
Device Good Manufacturing Practice Advisory Committee	0	33,649
Ear, Nose, and Throat Devices Panel	29,801	36,980
Gastroenterology-Urology Devices Panel	17,638	30,226
General and Plastic Surgery Devices Panel	52,855	55,827
General Hospital and Personal Use Devices Panel	0	46,393
Hematology and Pathology Devices Panel	23,598	25,961
Immunology Devices Panel	25,295	74,650

	1989 actual	1990 estimated
Microbiology Devices Panel	32,798	36,735
Neurological Devices Panel	15,845	29,050
Obstetrics-Gynecology Devices Panel	45,093	53,395
Ophthalmic Devices Panel	58,723	70,838
Orthopedic and Rehabilitation Devices Panel	41,862	54,259
Radiologic Devices Panel	22,418	37,384
Technical Electronic Product Radiation Safety Standards Committee	0	24,101
Veterinary Medicine: Veterinary Medicine Advisory Committee	49,408	54,770
National Center for Toxicological Research: Science Advisory Board	15,698	23,763

[1] New 1990

MINOR USE DRUG RESEARCH PROGRAM

Mr. WHITTEN. Please update the Committee on the agency's recent work in its minor use drug research program.

Mr. BENSON. I would be pleased to provide a summary for the record.

[The information follows:]

The overall objectives of this research program is to investigate the comparative physiology, metabolism, pharmacology, and toxicology of major and minor animal species (cattle, chickens, turkeys, ducks, sheep, rabbits, pheasants, quail, goats and catfish) and to study the applications and limitations of pharmacokinetic parameters as a basis for the extrapolation of data from approved major use drugs to minor use drugs for fish, gamebirds and other food animals. Some of the aforementioned research has contributed to the completion of Public Master File—3872 for the use of decoquinate premix for the prevention of coccidiosis is sheep. The availability of data from this public master file will be published in the Federal Register within 2 months.

Three cooperative agreements were awarded in FY 85 to the University of Florida, the Medical College of Wisconsin, and New York University Medical Center based on scientific merit and program relevance. These three cooperative agreements were awarded for three to four years (1985–1989). As satisfactory progress was made during the second year, the aquatic animal drug cooperative agreements were extended for a third year and fourth year. The objectives of these agreements were (1) to investigate the absorption, disposition and depletion of animal drugs (sulfadimethoxine and erythromycin thiocyanate); (2) to investigate the metabolic profiles of these drugs in muscle, liver or its equivalent, such as urine and feces; (3) to investigate the pharmackinetic parameters of drugs in aquatic animals; and (4) to compare metabolic profiles observed in aquaculture species (lobster, channel catfish and rainbow trout) with those found in mammalian species. The agency supported this research because there is a need for approved drugs in aquatic animals used for food. Furthermore, the aquaculture industry does not appear to provide sufficient markets for minor use drugs to justify the expenditure of research and development resources by drug sponsors.

COOPERATIVE AGREEMENTS IN THE AMOUNT OF $621,955 AWARDED FROM 1984 to 1989

Project title, contractor/awardee and principal investigator	Funding	Fiscal year
Drug Metabolism in Invertebrates—University of Florida, Dr. M. James	$64,530	1985
40,000		1986
40,423		1987
23,460		1988
Drug Metabolism in Fish—Medical College of Wisconsin	69,849	1985
38,000		1986
86,476		1987
31,886		1988
6,742		1989

COOPERATIVE AGREEMENTS IN THE AMOUNT OF $621,955 AWARDED FROM 1984 to 1989—Continued

Project title, contractor/awardee and principal investigator	Funding	Fiscal year
Metabolic Profiles and Pharmacokinetics of Drugs in Striped Bass, the Northern Lobster—NYU Medical Center, Dr. J. O'Connor	68,952	1985
	37,000	1986
	77,421	1987
	36,216	1988
Total	620,955	

Mr. WHITTEN. Also for the record, please list the public master files published in fiscal years 1989 and 1990 to date and the public master files currently under review by the agency related to minor use drugs.

Mr. BENSON. I would be happy to.

[The information follows:]

There are five public master files (PMFs) published in the Federal Register from 1989 to 1990.

PUBLIC MASTER FILES PUBLISHED IN 1989 AND 1990

PMF and drug		Species	Disease	Date of publication
3883	Ivermectin	Goats	Gastrointestinal parasites	Mar. 24, 1989.
5020	Salinomycin	Quail	Coccidiosis	r. 22, 1989.
5042	Lasalocid	Rabbits	do	15, 1990.
5071	Fenbendazole	Bighorn Sheep	Lungworms	Feb. 14, 1989.
5117	Levamisole HCL	Goats	Gastrointestinal parasites	Sept. 8, 1989.

There are five public master files under review by the Center for Veterinary Medicine.

PMF and drug		Species	Disease
3543	Formalin	Shrimp	Protozoa.
3872	Decoquinate	Sheep	Coccidiosis.
5059	Ivermectin	American Bison	Hypodermosis.
5118	Fenbendazole	Goats	Gastrointestinal parasites.
5206	Sulfamethazine	do	Bacterial pneumonia.

NUMBER OF EMERGENCIES

Mr. WHITTEN. For the record, please update the table that appears on page 805 of last year's hearing record related to emergency tampering complaints and threats.

Mr. BENSON. I would be happy to.

[The information follows:]

EMERGENCIES, TAMPERING COMPLAINTS AND THREATS—FISCAL YEARS 1984-89

	1984	1985	1986	1987	1988	1989
Tampering complaints	488	129	1,706	765	281	378
Tampering threats [2]	([1])	([1])	253	142	34	6
Other emergencies (excludes number of Class I recalls issued)	45	255	638	472	147	189
Total	533	384	2,597	1,379	462	573

[1] FDA did not keep records on tampering threats as a separate category in 1984 and 1985.

[2] FY 1986-1988—Includes **false** tampering reports. FY 1989—Excludes **False** Tampering reports.

AIDS RESOURCES

Mr. WHITTEN. Please provide an object class table for the resources available for AIDS for fiscal years 1989, 1990 and 1991.

Mr. BENSON. I will be happy to do so.

[The information follows:]

FDA RESOURCES FOR AIDS 1989-1991

[Dollars in thousands]

	1989	1990	1991
Personnel compensation and benefits	23,183	25,597	31,336
Travel and transportation	385	400	450
Rent, communications, and utilities	360	374	400
Printing and reproduction	502	522	545
Contracts and other services	14,454	16,440	17,100
Supplies and materials	4,825	5,018	5,220
Equipment	7,566	7,869	8,185
Total operating	51,275	56,220	63,236
Construction	22,500		
Total	73,775	56,220	63,236

DRUG APPLICATIONS

Mr. WHITTEN. Please submit for the record a table on drug applications similar to the one that appeared on page 827 of last year's hearing record.

Mr. BENSON. I would be pleased to submit that information for the record. This data represents our latest estimates of anticipated workloads.

[The information follows:]

DRUG APPLICATION SUMMARY

	Fiscal year—				
	1987	1988	1989	1990[1]	1991[1]
INDs:					
Number received	1,404	1,319	1,337	1,350	1,350
Reviews/action	3,488	2,383	2,244	2,700	2,700
Number active-end of year	9,945	9,678	9,500	9,700	9,700
NDA's:					
Applications received	121	134	119	125	125
Total applications	260	300	293	285	295
Number awaiting action over 180 days-end of year	140	83	87	100	90

DRUG APPLICATION SUMMARY—Continued

	Fiscal year—				
	1987	1988	1989	1990[1]	1991[1]
Total number approved	77	68	79	75	75
Time from receipt to approval (mean)	(26.7)	(29.6)	(29.9)	(23–30)	(23–30)
NDA Supplements:					
Original and resub. received	3,415	3,146	3,151	3,300	3,300
Total actions	2,273	2,240	2,427	2,300	2,300
Number awaiting action-end of year	2,588	2,043	1,899	2,200	2,200
Supplements approved	1,452	1,215	1,457	1,400	1,400
ANDA's:					
Original ANDAs Received	988	842	900	360	600
Resubs, amendments, supplements, reports, corres	23,648	20,752	21,000	15,000	17,000
Review original form 6's	122	179	206	140	180
Resubs, amendments, supplements, reports, corres	5,174	5,121	5,200	5,200	5,200
Total number approved	650	752	364	80	240
Average review time from receipt to approval (months)	14.7	16.0	20.5	22.0	22.0

[1] Estimate.

BLUE RIBBON PANEL

Mr. WHITTEN. In the past several months, the FDA has been severely criticized for its work related to the generic drug program. Late last year the Secretary for Health and Human Services, Dr. Sullivan, announced that he would institute a Blue Ribbon Panel to review the entire Food and Drug Administration's approach to the generic drug activity. While we know that Dr. Sullivan recently announced the head of the panel, what is the status of this proposed panel?

Mr. BENSON. The actual appointment of members to the committee is subject to the prescribed HHS appointment procedures, which should be completed within the next few weeks. Committee Chairman Charles Edwards said he expects that HHS will complete the process quickly, adding that he expects to convene the inaugural meeting sometime in May.

The committee's job will be to examine FDA's mission, responsibilities and structure and to make recommendations, over the next year, for improving the agency's operations and effectiveness in the future.

[CLERK'S NOTE.—Subsequent to the hearing, Dr. Sullivan announced on March 22, 1990 the names of individuals whom he has selected to serve on the Advisory Committee on the Food and Drug Administration.]

DRUGS MANUFACTURED OVERSEAS

Mr. WHITTEN. We know that the FDA approves drugs manufactured overseas for marketing in the United States. Do the manufacturing practices of foreign companies receive the same scrutiny as do domestic companies? What resources were expended annually during fiscal years 1989, 1990 and 1991 for international review of manufacturing practices related to drugs and devices?

Mr. BENSON. Foreign drug and device manufacturers must meet the same FDA manufacturing practice standards for the production of safe products as U.S. manufacturers. Surveillance may take different avenues, such as screening foreign imports at the port of entry to ensure safety and the establishment of Memoranda of Understanding with foreign governments so that we can use the regulatory capability of the other country, but the manufacturing practices of both domestic and foreign manufacturers are reviewed equally in terms of the requirements for approval.

FDA devoted 15 FTEs to inspection of manufacturing practices of foreign drug and device establishments in 1989 and we expect this number to remain about the same in 1990 and 1991.

BLOOD BANK INSPECTIONS

Mr. WHITTEN. Because of safety concerns related to AIDS and hepatitis, the FDA launched a program to inspect every FDA-regulated blood bank and plasma center annually. This program has been going on for approximately two years, but you continue to find major deviations from standards. What action is FDA taking to correct these deviations?

Mr. BENSON. The deviations we are finding are a reflection of the growing sophistication and effectiveness of our inspections. For example, our investigators, who have been receiving more intensified training, are better prepared to uncover deviations, especially in the areas of testing for hepatitis b and HIV-1. Educational efforts with the industry have led to increased self-examination by blood banks which have uncovered deviations and have led to a number of recalls. During 1989, we classified and published 228 recall actions involving blood, blood components, or plasma. This represents an increase of 170% over the 84 recalls published in 1988.

Our corrective actions are directed to bringing about resolution through more effective identification of problems both by the FDA and industry and by regulatory enforcement actions when necessary. These actions involve the provision of updating training to FDA investigators; participation in educational programs sponsored by trade and professional organizations representing the blood and plasma industry; and communication of our policy decisions, new testing methodologies, and new data more effectively to industry through written memoranda. These memoranda serve as a means to disseminate important information as rapidly as possible to these establishments. Examples include, "Guidance for Autologous Blood Collection and Processing", and "Requirements for Computerization of Blood Establishments." In addition, we are developing new regulations to address issues identified through inspections, an example of which was an FDA proposal of a rule in June, 1989 to describe a requirement whereby each establishment or laboratory, responsible for performing FDA-required tests, must participate in an approved program to demonstrate proficiency in performing these tests. Other actions include utilizing enforcement actions in significantly violative situations, and classifying recall actions according to degree of seriousness.

Mr. WHITTEN. Since you began this program during 1988, how many blood banks have been shut down as a result of an FDA enforcement action?

Mr. BENSON. Two facilities had their licenses revoked in 1988, and the license of one facility was revoked in 1989.

I would like to add that FDA has a number of enforcement action options which are used to secure compliance by blood banks. To focus on just those actions that result in the shut down of a blood facility would be taking, I believe, a very restrictive view of the options. For example, regulatory letters have proved very effective in convincing blood banks to correct deviations. Twenty-six regulatory letters were issued in 1988, and 29 were issued in 1989. There were 5 actions taken in 1988 to suspend licenses and 6 actions taken in 1989. The administrative remedies of license suspension and revocation have proved to be powerful deterrents for those blood banks engaged in interstate commerce.

After significant deviations were uncovered at a number of American Red Cross facilities, FDA and the American Red Cross signed an agreement under which they were to make improvements nationwide. Subsequent surveillance by FDA is indicating a significantly higher rate of compliance. This agreement was comparable to the issuance of approximately 56 regulatory letters which was not reflected in the number of regulatory letters issued in 1988 and 1989.

ADVERSE DRUG REACTION REPORTING SYSTEM

Mr. WHITTEN. The Food and Drug Administration has several pilot projects relating to reporting of adverse drug reactions. You have awarded contracts with the States of Maryland, Rhode Island, Mississippi, Massachusetts and Colorado. For the record, please provide a brief description of the results from these contracts and what actions FDA intends to take as a result of its findings.

Mr. BENSON. Maryland and Rhode Island were awarded the first two pilot test contracts. The objectives of these contracts were to develop programs designed to measure the existing level of physician knowledge of and attitudes toward adverse drug reaction reporting, develop educational and promotional interventions to stimulate awareness and promote reporting, and determine the effectiveness of the intervention by conducting a follow-up survey of physician attitudes and knowledge with respect to reporting. Through these surveys, it was learned that the major barriers to reporting included a serious lack of awareness of the existence of FDA's spontaneous reporting system, unavailability of reporting forms, and confusion about what information to report. Based on this information, basic promotional and educational strategies were developed by the investigators to enhance use of the system.

The Maryland contract expired in 1988. New contracts were awarded to Rhode Island and Mississippi in early 1989 with objectives which include expansion of the existing programs to hospitals and nursing homes, testing the use of FDA's PC-based system, evaluation of acceptance by the medical community and further assessment of the educational interventions.

The ongoing contract with Colorado has resulted in a four-fold increase in reporting. Successful interventions have included presentations on adverse drug reaction reporting to targeted hospitals, quarterly newsletters about the methods and importance of reporting, and, expansion of the program's physician mailings on the adverse reaction reporting system.

Unfortunately, the Massachusetts program has not met our expectations and will likely be terminated with the expiration of the current contract this spring. Although the contractor has made every effort to meet the terms of the contract, there was apparently little local support in the medical and hospital community, and the hospital pharmacists were not involved early in the project.

Within the resources available, FDA plans to continue this type of effort to improve reporting of adverse drug reactions, with the overall goal of enhancing the agency's ability to detect adverse reactions not previously known.

FAIR PACKAGING AND LABELING ACT

Mr. WHITTEN. Please describe your activities related to the Fair Packaging and Labeling Act in fiscal years 1989 and 1990.

Mr. BENSON. As in past years, in 1989 and continuing into 1990, FDA field offices have conducted product inspections for adulteration and misbranding violations under the agency's Domestic and Import Food Labeling and Economics Compliance Programs. These programs are designed to detect those products whose composition or labeling are likely to mislead or deceive consumers about the economic value of the product. The programs direct particular attention to substitute products that are not properly labeled as such, and to products that are not in compliance with their labeled net weights. These short weight products may include nuts, instant tea, instant coffee, spices and overglazed seafoods. These inspections are conducted in conjunction with other inspection programs such as the Food Safety Compliance Program. FPLA activity by the field in FY 1989 included 46 inspections, 18 domestic sample analyses, 326 import sample collection, and 676 import wharf examinations. Although there is no specific data reporting system in place for FPLA activities in the area of cosmetics, the agency's general data reporting system includes FPLA activities related to cosmetics, such as collections to monitor cosmetic ingredient declarations.

IMPORT TEA ACT

Mr. WHITTEN. Please describe your activities related to the Tea Importation Act in fiscal years 1989 and 1990.

Mr. BENSON. In FY 1989 and 1990, FDA continued tea examination activities through field compliance programs in two FDA ports of examination, New York and New Orleans. The compliance program requires that each line in every invoice of whole leaf tea presented for import be considered for examination by FDA tea examiners. The examination is based upon tea standards established annually by the Board of Tea Experts. In FY 1989, about 187 million pounds of tea were examined, representing a decrease of approximately 1 million pounds from the volume examined in FY 1988. During FY 1989, 0.13 percent of the teas offered for import did not conform to the standards of purity, quality, and fitness for consumption mandated by the Tea Importation Act and the agency's implementing regulations in 21 CFR Part 1220.

IMPORT MILK ACT

Mr. WHITTEN. Please describe your activities related to the Import Milk Act in fiscal years 1989 and 1990.

Mr. BENSON. The activities in 1989 and 1990 involved the review of two applications to import frozen cream into this country under the Import Milk Act. In order to determine whether there is compliance with the requirements of the Import Milk Act, FDA reviews records about the physical examination of all cows in the herd, the tuberculine testing of all cows, inspection of each dairy plant processing or handling the cream and milk for import, sanitary inspection of the dairy farms, and a certified statement that all work was performed by duly accredited officials of the foreign governments. FDA activities relating to the Import Milk Act also included telephone inquiries, meetings, and written correspondence about the requirements for the importation of milk and cream products into this country. We expect FDA's activities in FY 1991 to involve the same general activities.

HEALTH FRAUD

Mr. WHITTEN. Please provide for the record a copy of FDA's annual status report on health fraud for 1989.

[CLERK'S NOTE.—The report is too lengthy for reprint. A copy has been retained in Committee files.]

Mr. WHITTEN. What resources did FDA commit to health fraud in fiscal years 1989 and 1990, and what do you anticipate spending in fiscal year 1991?

Mr. BENSON. In fiscal year 1989 we expended 41 FTEs and $2.7 million for health fraud activities. We plan to expend 46 FTEs in FY 1990 at a cost of $3.0 million, and 48 FTEs in FY 1991 at a cost of $3.4 million.

FIELD LABORATORIES

Mr. WHITTEN. We are aware that several of the FDA regional laboratories are in serious need of repair and, in fact, buildings in which they are located are inadequate for current Good Laboratory Practices (GLP). Laboratories in Los Angeles, Seattle, San Francisco, and recently announced Kansas City, have all been projected to move into newer space and update equipment. For the record, please provide a short detailed description of each of the laboratories in terms of its specialty and any future plans for moving into newer building space.

Mr. BENSON. FDA field laboratories, in general, perform analysis of food, drug, cosmetic, veterinary drugs and medical device products which are regulated by the FDA. These are regulatory laboratories whose analytical workloads vary depending on the industries which are located within the respective districts.

Recently, two of eighteen field facilities have relocated and seven more moves are scheduled by 1993. For the most part, these moves are necessary due to lease expirations with the exception of Brooklyn and San Francisco. These two districts are located in government owned buildings which are no longer adequate to support laboratory operations. I would be happy to provide for the record profiles of each laboratory indicating any specialty analytical work performed and future relocation plans, if applicable.

[The information follows:]

NORTHEAST REGION

Winchester Engineering & Analytical Center, Winchester, MA 01890.

Lease Expiration: FDA owned.

Profile: Provides general analytical work for the Boston District and is the medical device/radiation specialty lab. Since this facility is Agency owned, all maintenance, operation and utility expenses are funded by FDA.

Buffalo District, Buffalo, NY 14202.

Lease Expiration: September 1993.

Profile: Provides general analytical work for the Buffalo District and has special expertise in pesticides and heavy metals.

New York District Offices, Brooklyn, NY 11232.

Proposed Relocation: December 1993.

Profile: Provides laboratory support services for the Northeast Region, the New York District with an emphasis on imports. Support services include NRM, mass spectrometry, pesticide residue analysis, heavy metals, etc. Recent meetings with GSA have resulted in the decision to relocate FDA to more suitable facilities.

San Juan District, San Juan, PR 00906.

Lease Expiration: FDA owned.

Profile: The San Juan laboratory is an all purpose lab which can analyze food, drugs, pesticides and microbiological samples. Since the facility is Agency owned, all maintenance, operation and utility expenses are funded by FDA.

MID-ATLANTIC

Philadelphia District Office, Philadelphia, PA 19106.

Lease Expiration: Government owned.

Profile: Provides general laboratory support services including food and color additives, drug quality assurance and biotechnology for the Philadelphia district.

Baltimore District, Baltimore, MD 21201.

Lease Expiration: January 1994.

Profile: The Baltimore laboratory is a general purpose lab providing pesticide, microbiological and drug analyses for the district.

Cincinnati District, Cincinnati, OH 45202.

Lease Expiration: July 1991.

Proposed Relocation: August 1992.

Profile: In addition to providing drug and microbiological analytical work for the district, the Cincinnati laboratory also houses the FDA Forensics laboratory, for which additional federal support in the 1991 budget request.

SOUTHEAST REGION

Atlanta District Office, Atlanta, GA 30309.

Lease Expiration: November 2005.

Profile: This is a Regional lab providing broad laboratory support for the Atlanta, Orlando and Nashville districts. Specialized work includes microbiological hazards and sterility, aflatoxin and pesticide analyses in foods and human drugs and the Center for Nutrient Analysis.

New Orleans District, New Orleans, LA 70122.

Lease Expiration: July 1998.

Profile: Provides basic laboratory support services for the district and specializes in analyzing for aflatoxins and other mycotoxins. This lab also houses the Natural Toxins Research Center.

MIDWEST REGION

Chicago Laboratory, Chicago, IL 60616.

Lease Expiration: November 1992.

Profile: Provides basic lab services and performs all dioxin work for the field. The lab is also highly experienced in automated drug analysis and in color additives analysis.

Minneapolis District, Minneapolis, MN 55401.

Lease Expiration: February 1992.

Proposed Relocation: December 1992.

Profile: This is an all purpose lab which analyzes food, drug, and pesticide samples and specializes in microbiological analysis and sterility analysis.
Detroit District, Detroit, MI 48207.
Lease Expiration: May 1993.
Profile: This is a general purpose lab specializing in drug analysis. The Detroit lab also includes the Pesticide and Industrial Chemical Research Center.

SOUTHWEST REGION

Dallas District, Dallas, TX 75204.
Lease Expiration: January 1992.
Proposed Relocation: December 1992.
Profile: The Dallas laboratory is an all purpose lab which analyzes foods, and drugs, pesticides and microbiological samples.
Kansas City District, Kansas City, MO 64106.
Lease Expiration: December 1990.
Proposed Relocation: February 1991.
Profile: The Kansas City lab is a general purpose facility and also specializes in total diet market basket program and accompanying research at the Total Diet Research Center.
Denver District, Denver, CO 80225.
Lease Expiration: Government owned.
Profile: This new laboratory recently provided for FDA specializes in microbiological and animal drug analyses. The Animal Drug Research Center is also located in this facility.

PACIFIC REGION

San Francisco District, San Francisco, CA 94102.
Lease Expiration: Government owned.
Proposed Relocation: October 1992.
Profile: This is a general purpose laboratory which provides basic lab support services including pesticides, food and color additives and microbiological analyses. FDA and GSA have mutually agreed to relocate this facility as we are the only laboratory in the building. As a result, we are pursuing a lease in the Post Office building.
Los Angeles District, Los Angeles, CA 90015.
Lease Expiration: Expired.
Proposed Relocation: September 1991.
Profile: This is a general purpose laboratory specializing in pesticide residue analysis.
Seattle District, Bothell, WA 98021.
Lease Expiration: Government owned (new facility for FDA recently occupied).
Profile: The Seattle laboratory is a general purpose lab and also houses the Seafood Products Research Center.

SMALL MANUFACTURERS OF MEDICAL DEVICES

Mr. WHITTEN. Please provide a table showing a five-year history of the amount of funds allocated to assist small manufacturers of medical devices. Include the amount proposed for fiscal year 1991. Are there any requests by small businesses to which FDA has not responded?

Mr. BENSON. We will provide for the record the resources devoted to this program. Part of FDA's mandate is to provide technical and non-financial assistance to makers of medical devices in meeting regulatory requirements, and we have increased our staffing in this function so that we can continue to provide assistance in a timely fashion. I am not aware of any instances where FDA has not responded to a request, although we may not always be able to provide as much assistance as someone expects.

[The information follows:]

DEVICE SMALL MANUFACTURERS ASSISTANCE

	FTE's	Thousands
Fiscal year:		
1986	11	$700
1987	13	800
1988	14	900
1989	14	1,000
1990	20	1,500
1991 estimate	22	1,700

SULFAMETHAZINE IN MILK

Mr. WHITTEN. Recent media reports have indicated that sulfamethazine, a suspected carcinogen, is prevalent in our Nation's milk supply. The press reports indicated that there is a significant difference between the results of FDA's tests on milk and those conducted by states and/or private laboratories paid for by the Wall Street Journal and others. Please explain for us the difference in the testing methods used by FDA and other parties.

Mr. BENSON. I appreciate the opportunity to do so, Mr. Chairman. In December of 1989, the Wall Street Journal reported that milk contained residues of antibiotics. This report was based on a survey of retail milk using the nonspecific Charm II antibiotic screen method as the exclusive method of analysis. The Wall Street Journal did not confirm its initial residue findings using a second, more specific, testing method.

FDA designed a survey to determine and confirm the extent of antibiotic residues that may be present in milk. FDA's survey consisted of 70 retail milk samples collected from 14 cities. In the survey design, FDA included the Charm II test because it had been used in the survey conducted by the Wall Street Journal, but relied primarily on multiresidue High Performance Liquid Chromatography procedures for sulfonamides and tetracyclines with major emphasis on verifying positive screening results with confirmatory methods.

All samples were analyzed for ten sulfonamides and three tetracyclines using High Performance Liquid Chromatography procedures, with mass spectrometry confirmation on any presumptive positives above the safe level. The High Performance Liquid Chromatography methods used by the Center for Veterinary Medicine for the 10 sulfonamides and the three tetracyclines have lower limits of detection for these antibiotics than the Charm II assay.

Using the sulfonamides High Performance Liquid Chromatography method, FDA found 11 samples which gave presumptive positives above 10 ppb—the designated level of concern. Of these, the 10 presumptive positives for sulfadiazine failed to confirm using mass spectrometry capable of detecting this sulfonamide at a level of 10 ppb. FDA is still analyzing the 11th presumptive positive. The Charm II assay limit of detection for sulfonamides is also 10 ppb. FDA is confident that if any of the ten sulfonamides had been present above the limits of detection of the High Performance Liquid Chromatography procedures that would have been detected.

At this time, we are also confident that if sulfamethazine and sulfadiazine had been found with High Performance Liquid Chromatography above 10 ppb we could have confirmed these compounds. FDA has previously confirmed sulfamethazine in milk at levels of 2–10 ppb.

For the three tetracyclines, the limits of detection do not achieve the designated level of no concern. However, since the Charm II assay is 4–6 times less sensitive than the High Performance Liquid Chromatography and two times less sensitive than the mass spectrometry for tetracyclines, we are also confident that had any of the samples which tested positive by the Charm II test contained the three tetracyclines, we would have detected their presence.

FDA results indicate that for the 70 retail milk samples collected from 14 cities, confirmed residues for the 10 presumed positive sulfadiazines were not found above 10 ppb. Further, residues above the detection limits of the High Performance Liquid Chromatography procedures for the three tectracyclines were not found.

Mr. Whitten. Has FDA changed any of its procedures in sampling of milk since these reports in late December and early January?

Mr. Benson. No, Mr. Chairman. We believe that our existing procedures are still valid.

ORPHAN PRODUCTS

Mr. Whitten. Please provide for the record an object class table of your expenditures in the orphan products area for fiscal years 1989, 1990, and 1991.

Mr. Benson. Of course, I will be happy to.

[The information follows:]

ORPHAN PRODUCTS EXPENDITURES, 1989–91

[In thousands of dollars]

	1989	1990	1991
Personnel compensation and benefits	1,760	1,857	1,931
Travel and transportation	30	30	31
Other services	132	135	140
Supplies and materials	178	183	198
Grants	5,400	7,500	7,770
Total	7,500	9,705	10,070

Mr. Whitten. What specific FTE resources has FDA committed to orphan product work for fiscal years 1989, 1990, and 1991?

Mr. Benson. FDA expects to utilize 33 FTEs in 1989, 1990, and 1991 for orphan product work.

Mr. Whitten. Please provide a list of all products approved as part of the orphan product authorities.

Mr. Benson. Certainly. I will be glad to do so.

[The information follows:]

APPROVED DESIGNATED ORPHAN PRODUCTS

1983

HEMIN - Hepatic Porphria

CHENODIOL - Dissolution of radiolucent Gallstones in poor surgical-risk patients

1984

PENTAMIDINE ISETHIONATE - For the treatment of Pneumocystis carinii pneumonia

NALTREXONE - narcotic addiction

CROMOLYN SODIUM 4% OPTHALMIC SOLUTION - Vernal Keratoconjunctivitis

1985

POTASSIUM CITRATE - Management of Renal Tubular Acidosis (RTA) with calcium stones, Hypocitraturic Calcium Oxalate Nephrolithiasisof any etiology, and Uric Acid Lithiasis with or without calcium stones

MONOOCTANOIN - Solubilizing Agent for Cholesterol (Radiolucent) Gallstones retained in the Biliary tract following Cholecystectomy, when other means of removing cholesterol stones have failed or cannot be undertaken

TRIENTINE - treatment of patients with Wilson's Disease who are intolerant of Penicillamine when continued treatment with penicillamine is no longer possible because of intolerable or life-endangering side effects

SOMATREM - For long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion

L-CARNITINE TABLETS - Treatment of primary systemic Carnitine Deficiency

1986

L-CARNITINE ENTERAL LIQUID - Treatment of primary Systemic Carnitine Deficiency

DIGOXIN - Specific antibody fragments - treatment of potentially life-threatening digitalis intoxication

UROFOLLITROPIN - For use in the induction of ovulation in patients with Polycystic Ovarian disease who have an elevated LF/FSH ratio and who have failed to respond to adequate clomiphene citrate therapy

CLOFAZIMINE - For the treatment of Lepromatous leprosy

TRANEXAMIC ACID - For the treatment of patients with hemophilia for short term use before and after tooth extraction to reduce or prevent hemorrhage and reduce the need for replacement therapy

CALCITONIN (Human) - For the treatment of symptomatic Paget's Disease of Bone Osteitis Deformans

1987

SOMATROPIN - For long-term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone

ZIDOVUDINE - Management of certain patients with symptomatic HIV Infection who have history of histologically confirmed *Pneumocystis carinii* pneumonia (PCP)

ETIDRONATE DISODIUM - Treatment of hypercalcemia of Malignancy inadequately managed by dietary modification and/or oral hydration

PENTASTARCH - Adjunct in Leukapheresis, to improve the harvesting of Leukocytes by centrifugal means

ALPHA-1-PROTEINASE INHIBITOR (Human) - Chronic replacement therapy of individuals having congenital deficiency of Alpha-1-Proteinase Inhibitor with clinically demonstrable panacinar emphysema

SODIUM BENZUATE AND SODIUM PHENYLACETATE - Adjunctive therapy for prevention and treatment of Hyperammonemia in the chronic management of patients with Urea Cycle Enzymopathies involving partial or complete deficiencies of carbamylphosphate synthetase, Ornithine Transcarbamylase, or Argininosuccinate Synthetase

TERIPARATIDE ACETATE - Diagnostic agent to assist in establishing the diagnosis in patients presenting clinical and laboratory evidence of hypocalcemia due to either hypoparathyroidism or pseudohypoparathyroidism

MITOXANTRONE HCL - For use in combination with other approved drugs in initial therapy of Acute Nonlymphocytic Leukemia in adults

1988

METHOTREXATE - For use with leucovorin rescue in combination with other chemotherapeutic agents to delay recurrence in patients with non-metastatic osteosarcoma who have undergone surgical resection or amputation for the primary tumor

THIOLA - For use in the prevention of cystine nephrolithiasis in patients with homozygous cystinuria

LEUCOVORIN CALCIUM - For rescue use after high dose methotrexate therapy in the treatment of osteosarcoma

INTERFERON ALFA 2A - For use in the treatment of selected patients with AIDS-related Kaposi's Sarcoma

INTERFERON ALFA 2B - For use in the treatment of selected patients with AIDS-related Kaposi's Sarcoma

METRONIDAZOLE - For use in the treatment of acne rosacea

ETHANOLAMINE OLEATE - For treatment of patients with esophageal varices that have recently bled, to prevent rebleeding

IFOSFAMIDE - To be used in combination with certain other approved antineoplastic agents, for third line chemotherapy of germ cell testicular cancer. It should ordinarily be used in combination with a prophylactic agent for hemorrhagic cystitis, such as mesna

MESNA - For use as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis

1989

SELEGILINE HCL - For use as an adjunct in the management of parkinsonian patients being treated with levodopa/carbidopy who exhibit deterioration in the quality of their response to this therapy

PENTAMIDINE ISETHIONATE (INHALATION) - For the prevention of Pneumocystis carinii pneumonia (PCP) in patients at high risk of developing this disease

GANCICLOVIR SODIUM - For use in the treatment of cytomegalovirus retinitis in immunocompromised individuals, including patients with acquired immunodeficiency syndrome

EPOETIN ALFA - For the treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis

RIFAMPIN - For antituberculosis treatment in cases where use of the oral form of the drug is not feasible

ANTITHROMBIN III - For the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism

CROMOLYN SODIUM - For the treatment of patients with mastocytosis

BOTULISM ANTITOXIN TYPE A - For the treatment of patients with strabismus and blepharostasm associated with dystonia in adults

NEFLOQUINE HYDROCHLORIDE - For the treatment of acute malaria due to Plasnodium falciparum and the Plasnodium vivax

ORPHAN GRANTS AND CONTRACTS

Mr. **Whitten**. Please provide a listing of all grants and contracts issued during fiscal year 1989 for orphan product work.

Mr. **Benson**. In addition to continuation funding of prior grants, 21 new grants were awarded. I will be happy to furnish a list of these awards.

[The information follows:]

ORPHAN GRANT AWARDS - 1989

Karl E. Anderson, M.D.
The University of Texas Medical Branch at Galveston
Galveston, Texas
Erythropoietin for Hemodialysis-Associated Porphyria

Paul A. Boepple, M.D.
Massachusetts General Hospital
Boston, Massachusetts
GnRH Analogues and Final Height in Precocious Puberty

Richard I. Breuer, M.D.
Evanston Hospital Corporation
Evanston, Illinois
Short-Chain Fatty Acid Therapy of Ulcerative Colitis

George J. Brewer, M.D.
University of Michigan
Ann Arbor, Michigan
Maintenance Therapy of Wilson's Disease with Zinc

George J. Brewer, M.D.
University of Michigan
Ann Arbor, Michigan
Therapy of Wilson's Disease with Tetrathiomolybdate

Saul W. Brusilow, M.D.
Johns Hopkins University
Baltimore, Maryland
Urea Cycle Enzymopathies; Phase III Studies of PhenylbutyricAcid

Henry Buchwald, M.D., Ph.D.
University of Minnesota
Minneapolis, Minnesota
New Peritoneovenous Shunt for Treatment of Ascites

J. Julian Chisolm, Jr., M.D.
The Kennedy Institute for Handicapped Children, Inc.
Baltimore, Maryland
Safety and Efficacy of DMSA in Therapy of Lead Poisoning

Robert E. Dudley, Ph.D.
Gynex, Inc.
Deerfield, Illinois
Low Dose Ethinyl Estradiol for Gonadal Failure

Barbara Helen Herman, Ph.D.
Children's Hospital National Medical Center
Washington, D.C.
Evaluation of Naltrexone in Autistic Children

Mark Andrew Jacobson, M.D.
University of California, San Francisco
San Francisco, California
Rifampin/Ethambutol/Ciprofloxacin Treatment for M.Avium Complex

Kenneth E. McMartin, Ph.D.
Louisiana State University Medical Center in Shreveport
Shreveport, Louisiana
4-Methylpyrazole: Methanol/Ethylene Glycol Antidote Study

Shirley I. Miekka, Ph.D.
American Red Cross
Rockville, Maryland
Clinical Studies of Coagulation Factor X

Richard D. Penn, M.D.
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois
Intrathecal Baclofen for Severe Spasticity

Ananda S. Prasad, M.D., Ph.D.
Wayne State University
Detroit, Michigan
Clinical Trial of Zinc in Sickle Cell Anemia

James C. Sisson, M.D.
University of Michigan
Ann Arbor, Michigan
Radiopharmaceutical Treatment of Neuroblastoma

Georgia B. Vogelsang, M.D.
The Johns Hopkins University School of Medicine
Baltimore, Maryland
Thalidomide vs Prednisone for Treatment of Chronic Graft-vs-Host Disease

Gerald D. Weinstein, M.D.
University of California, Irvine
Irvine, California
Photofrin II Photodynamic Therapy of Severe Psoriasis

William G. Wilson, M.D.
University of Virginia
Charlottesville, Virginia
Betaine in the Treatment of Homocystinuria

Walter Wolf, Ph.D.
Professional Staff Association
Los Angeles, California
195mPt-Cisplatin, Drug Monitoring, Effectiveness/Safety

Alice L. Yu, M.D., Ph.D.
The Regents of the University of California
La Jolla, California
Clinical Trial of an Anti-GD2 Mab in Neuroblastoma

WASHINGTON AREA FACILITIES

Mr. **WHITTEN**. FDA Headquarters is currently occupying space in several buildings in the Washington Metropolitan Area. For the record, please provide a listing of all buildings occupied by FDA Headquarters personnel. Also provide information on the annual rental cost for each building, the number of personnel in each, and the average square feet per employee in each building. Also, please provide a general description of the center or work that is occupying that particular building.

Mr. **BENSON**. I would be happy to provide that information for the record.

[The information follows:]

FDA Current Space-Washington Metropolitan Area

Building/Location	Annual Cost Rent ($000) 5/	Total Personnel	Office Utilization Rate (Sq.Ft)	Building 4/ Utilization Rate (Sq.Ft)	Center Ocupying Building
Rent Paid to GSA 1/					
Switzer Building 330 C Street, SW Washington, D.C. 20201	585	86	166	197	Ctr. for Food Safety and Applied Nutrition
12709 Twinbrook Pkwy. Rockville, MD 20852	374	53	125	359	Ctr. for Devices & Radiological Health
12720 Twinbrook Rockville, MD 20852	742	177	133	235	Ctr. for Devices & Radiological Health
12721 Twinbrook Rockville, MD 20852	264	33	172	452	Ctr. for Devices & Radiological Health
1901 Chapman Avenue Rockville, MD 20852	828	161	156	238	Ctr. for Devices & Radiological Health
7520 Standish Place Rockville, MD 20855	702	246	161	168	Ctr. for Biologics/ Ctr. for Drugs
1390 Piccard Avenue Rockville, MD 20850	1,620	464	126	158	Ctr. for Devices & Radiological Health
FB-8 2nd and C Streets, SW	11,432	862	152	381	Ctr. for Food Safety and Applied Nutrition

12420 Parklawn Drive Rockville, MD 20852	540	169	143	326	Office of the Commisioner Ctr. for Biologics/ Ctr. for Drugs
5600 Fishers Lane Rockville, MD 20852 Commissioner	4,956	2,279	151	169	Hdqtrs for FDA/ Office of the Ctr. for Drugs/ Ctr. for Veterinary Med.
Payments to Other Agencies 2/					
Agricultural Research Ctr. East Bldg. #328A Beltsville, MD 20705	345	44	261	814	Ctr. for Veterinary Medicine
Bldgs 29, 29A,and 14 NIH Campus 9000 Rockville Pike Bethesda, MD 20892	6,042	450	161	168	Ctr. for Biologics
Direct Lease 3/					
5516 Nicholson Lane I, II, III Rockville, MD 20852	2,163	181	162	306	Ctr. for Biologics/ Ctr. for Drugs
4 Research Court Rockville, MD 20850	65	12		208	Ctr. for Drugs
11400 Rockville Pike Rockville, MD 20852	42	11	227	227	Ctr. for Drugs
12100 Wilkins Avenue Rockville, MD 20852	60	0		0	Warehouse
12200 Wilkins Avenue Rockville, MD 20852	500	54	119	351	Ctr for Devices and Radiological Health

12290 Wilkins Avenue Rockville, MD 20852	28	0		0	Warehouse
FDA - Owned Buildings					
Beltsville Research Facility Rt #2, Box 277 Muirkirk & O'Dell Rds Laurel, MD 20708	0	31	265	1,581	Ctr. for Food Safety and Applied Nutrition/ Ctr. for Drugs/ Ctr. for Veterinary Med.
TOTAL	31,288 5/	5,315	150	258	

1/ GSA Rent - FDA pays $3,987,491 in operating costs over and above rent for these buildings.

2/ The annual cost FDA pays to other agencies for occupying these locations pays for support services.

3/ Direct Leases - FDA will pay $677,448 in expense for these buildings in addition to lease costs.

4/ Average building utilization rate includes office, special purpose and laboratory space.

5/ Reflects billings received from GSA; due to the Congressional limitation on rental payments to GSA, FDA only pays $25,612,000 in total.

MODULE 1

Mr. **Whitten**. Several years ago Congress provided funds to construct what is referred to as Module 1 at the Beltsville Center for FDA purposes. The building is still vacant and sitting there. The press continually reports about the problems of lack of FDA space. For the record, please provide us the total cost of construction of that facility and tell us the status of Module 1 and explain why FDA has not occupied the facility.

Mr. **Benson**. Total cost of construction of Module 1 as of April 1, 1990 is approximately $30,000,000. Certain elements of the building are not yet complete because some work, originally done by the contractor, did not conform with contract drawings or specifications. Reconstruction work is expected to be complete by October 1, 1990 and FDA hopes to be able to occupy the new facility shortly thereafter. Major problems experienced during construction of Module 1 have included problems such as the exterior masonry cavity wall system with steel stud backup, which had to be completely dismantled and re-constructed.

Also, there was failure of the epoxy paint system on concrete block walls due to the contractor's use of non-conforming block filler. This product substitution required extensive sand-blasting to remove incorrect block filler so that proper paint system could be applied.

Failure of some supply fans to conform to contract performance requirements required replacement of the fans. Failure of quantitative air control system elements to meet performance requirements required extensive dismantling of HVAC systems and total replacement of constant volume regulator units and control elements. This work is ongoing and is expected to be finished by May 1, 1990.

Another non-conforming work element was the failure of veneer plaster ceilings to meet intended performance requirements which necessitated dry wall overlayment of failed ceilings and repainting of these ceilings. Overlayment of ceilings is completed but application of the coating system is not yet underway. This work is expected to be completed by July 31, 1990.

NCTR WATER SYSTEM

Mr. **Whitten**. In Fiscal Year 1990, Congress provided $300,000 for architectural and engineering work involved in the rehabilitation of potable water treatment facility and distribution systems at the National Center for Toxicological Research at Pine Bluff, Arkansas. Has a contract been issued for the A & E work?

Mr. **Benson**. Yes. The design has been completed.

Mr. **Whitten**. What is the total cost of replacing the potable water system at the NCTR complex?

Mr. **Benson**. About $1.7 million will be needed to replace the potable water system at the NCTR complex. This includes rehabilitation of the water treatment plant, replacing the distribution system, and repairing storage tanks. FDA plans to use its 1990 Buildings and Facilities funds to meet this need.

FIELD FACILITIES REPAIRS

Mr. **Whitten**. There are a significant number of district offices and regional laboratories of the FDA that are in need of repair and replacement of physical structures. Please provide a record of the backlog of known buildings and facilities requirements.

Mr. **Benson**. Current plans call for the relocation of a number of district offices and regional laboratories, but there will remain a number of field labs where fumehoods, lab casework, HVAC equipment, and utility systems are 25 years old or older and where significant infrastructure improvements are needed. This work consists primarily of repair or replacement of fumehoods, replacement of lab benches, replacement, or upgrading of HVAC systems and air filtration systems, upgrading of utility systems, creation of suitable facilities for temporary on-site storage of spent chemicals and reagents, renovation to labs incident to installation of equipment, etc. The estimated cost for these improvements for our field laboratories is $6,800,000. In view of competing priorities, we have identified $2.6 million of the most needed projects for which funding is included in our 1991 request.

PLANS FOR FY 90 BUILDING AND FACILITIES FUNDS

Mr. **Whitten**. For fiscal year 1990 Congress provided a significant increase to the Buildings and Facilities account to address some of FDA's physical structure needs. Please describe for us the allocation of these funds, and specifically, a brief description of each of the projects that is going to be funded with the $8,350,000 provided.

Mr. **Benson**. I would be happy to provide that information for the record.

[The information follows:]

Current plan for 1990 buildings and facilities funds

Work needed to complete module No. 1	$885,000
Consolidation plan (through GSA) (Development of program of requirements)	1,200,000
Foods—Renovation of FB-8 labs and Dauphin Island, Alabama Reseach Lab	300,000
Biologics—Miscellaneous renovations to building 29	200,000
Center for veterinary medicine—Modify/install new safety showers	25,000
Center for devices and radiological products—Animal care facilities	100,000
NCTR—Water system rehabilitation and other miscellaneous repairs	1,800,000
Field Facilities—General repairs and improvements to FDA field facilities nationwide such as replacement of fumehoods and upgrading lab electrical service	340,000
AIDS Building cost increase	3,500,000
Total 1990 appropriation	8,350,000

Mr. **Whitten**. Mr. Akaka?

SEAFOOD INSPECTIONS

Mr. **Akaka**. Thank you, Mr. Chairman.

Secretary Mason and Williams, Commissioners Benson and Holston, and Directors Levitt and Claunts, and Counsel Porter, I think it is an understatement for me to say that you have one of the toughest jobs. When you think about food, everybody consumes that. And today drugs have become so important.

As we improve technology and you begin to measure the traces it becomes much more difficult.

But I am going to confine my questions to one area. Seafood demand and consumption has increased dramatically. Because it has done so, we have found that much of our seafood is imported, so that constitutes a problem for us.

The problems have become so complex that I assume there are some problems with agencies—I am talking about FDA and I'm talking about the Department of Commerce, and I am also talking about USDA—in an effort to centralize seafood inspection.

I guess if I were to ask you which agency should do it, I think you would think that FDA would. But I don't want to ask you that question. [Laughter.]

When are you going to resolve this tug of war between your sister agencies? Do you agree also that the responsibility for seafood inspection should be centralized? In what agency?

Mr. BENSON. You anticipate correctly.

I believe that the programs that are in place now and that we anticipate are doing well and will do even better at assuring a safe seafood supply to the American public and to the rest of the world.

We do import a lot of seafood, but we also export a lot of seafood, and it is very important to make sure that we make it clear to the people that we export to that our seafood is, in fact, safe and wholesome.

The program that FDA has and we work in conjunction with the Department of Commerce's National Marine Fisheries Service, is an effective one and I think is becoming more effective.

The Administration has said very clearly that they want the seafood program to stay with the Food and Drug Administration and with NOAA. They have described that program in budget terms and it includes a $9 million increase in appropriated funds. We are making that request today, as well as an additional $5 million to be collected via user fees, which, I might add, is an ongoing program with NOAA right now. They are actually doing that.

People are being confused about the data representing safety of seafood. I am personally convinced that seafood across the board is safe. If you take away raw shellfish it is even safer. Problems with raw shellfish are unfortunate, and it is something that we are addressing and we are trying to overcome, but it is going to take a lot of work.

We need to clean up the sewage out of the harvesting waters and make sure that we stop people from harvesting in waters that are, in fact, polluted. I think that will help to solve that problem.

As far as working with the USDA in terms of resolving the issue, I think that the starting point is to recognize that the program is with FDA right now and that any change to that requires some consideration on the part of others. There are meetings at high levels in the Administration that are happening now and that will happen next week that should resolve it, so we are working in that direction.

Mr. **Akaka**. You also mentioned that $9 million was to be used for expanding seafood activities. Would this be in inspection and monitoring activities?

Mr. **Benson**. Yes, sir. It would be. Right now we inspect annually about one-fourth of the seafood processors in this country. We target areas where we think there might be problems.

The additional resources will allow us to increase that number of inspections. Right now we sample a large number of imports—and detain, in fact, a large number of imports. We get complaints from the people that import that we are too rough on them. I believe very strongly that we need to make sure that we don't offer any advantages to exporting countries to this country. We need to have a level playing field. That is a very important thing to consider.

Both through our program of agreements with foreign countries in terms of the kinds of programs that they have in their country for staying on top of the seafood industry in those countries, as well as our own sampling of imports, we are trying to assure that level playing field. We will enhance those programs.

We will also enhance our working with States— especially in the shellfish area—to make sure the States are doing their part. We believe in a combined, synergistic effort.

We will also enhance our research activities. There are many contaminants, many different kinds of bacteria and viruses that seafood of various kinds are subject to. We want to make sure when we do sample that we are able to detect problems and prevent those from getting to the public.

RAW FISH

Mr. **Akaka**. Yes. You touched on a subject that is close to my heart. In Hawaii raw fish is a huge commodity there. We have consumed that for years. With our oriental population, this is also further enhanced.

What recommendations do you have for my constituents who eat raw fish products? And what kind of problems have you associated with the consumption of raw fish? The type of fish usually is tuna, and there are some other deep sea fish that are consumed for that purpose.

Mr. **Benson**. I have sitting behind me a microbiologist who is an expert in this area. I would be delighted to ask him to come up and answer fully.

This is Dr. Doug Archer, Deputy Director of our Foods Center. As he comes up, let me say that from the fin fish standpoint—that is, non-shellfish area—that if the fish are properly handled after catch and until they reach the consumer, that there should be no problem with that practice. It is a question of if things are being done properly. That is one area that we will address as we apply the so-called HACCP programs—the Hazard Analysis Critical Control Point programs—to make sure that everyone is properly focusing on any potential problem area like refrigeration.

Doug, would you answer more fully please?

Dr. **Archer**. The main hazard that we see from the consumption of raw fish in the form of sushi or sashimi are the anasakis parasites.

These worms would be very difficult to detect by eye. There are very elaborate methods that have been developed to detect them.

It is not a very common disease. We have estimated that somewhere between seven and ten cases per year in the United States would be the most we would see from all present consumption of sushi.

At our Dauphin Island facility in Alabama we have also developed a means of controlling that problem. Now, whether it is acceptable to sushi consumers is another matter. Simply blast-freezing the product and holding it at freezing temperatures for 48 hours is sufficient to kill the worms and thus remove the problem.

Mr. **Akaka**. That is a concern of some of my constituents who are in the business about freezing what we call sashimi fish before it is consumed. They have never done this before, so therefore the thought of freezing it is something that they don't want to do.

I was just wondering whether that is very necessary or whether it can continue as not being frozen before they serve it.

Dr. **Archer**. We have not mandated that procedure; we have only recommended it for types of fish for which it is appropriate. But without some process such as that—either the blast-freezing or the cooking of fish—there is an inherent risk. It is a very low risk, but yet there is a risk there.

Mr. **Akaka**. Is the risk higher in what you call anadromous types of fish, or fish that go up into freshwater?

Dr. **Archer**. Not necessarily. No. It has more to do with the ecosystem—particularly in the Gulf of Mexico there is a problem with the types of sea mammals that have migrated into the Gulf, which are the actual harbingers of the worms. It is a very complex life cycle that this worm goes through.

Mr. **Akaka**. From your information, what do you think about the Hawaii area fish?

Dr. **Archer**. We have surveyed the Hawaiian waters, as well as all of the coastal waters of the United States, and have not found a significant difference in the number of parasites in most of the coastal waters of the U.S., including Hawaii.

Mr. **Benson**. Our expert in seafood, a fellow by the name of George Hoskin, just came back from a vacation where he did considerable scuba diving off Maui, so evidently he wasn't too concerned about that.

Mr. **Akaka**. I wish I were there. [Laughter.]

FISH SEIZURES

What has been your experience over the past year with seizures of unsanitary or contaminated fish?

Mr. **Benson**. It should be pointed out that seizure is just one of the regulatory options available in dealing with seafoods found to be unsanitary contaminated. We also have recalls, citations and detentions to remove such products from the marketplace.

Regarding seizures, there were seven completed during 1989 involving a variety of products. Cod were seized for containing a filthy substance, namely parasitic cysts. Frozen fish labeled as Pacific Red Snapper and Imitation Crab Meat Flakes were seized because glycine, an unapproved food additive, was reportedly added to the products, and because they were misbranded. A Puerto Rico mass seizure was made against cod fish fillets for rodent contamination. A South Carolina seizure was made on frozen crabmeat containing insect and animal filth. An Illinois mass seizure included frozen scallops contaminated with rodent filth. A California seizure was made of frozen Tilapia for rodent filth, and a Florida seizure of frozen shrimp was made for contamination by insects and rodents.

For the current fiscal year we can report that several seizures have been completed to date. Lake Perch were seized in Wisconsin for insanitary conditions and economic fraud, and a mass seizure was made of all frozen seafood in paper, glass and metal cans for being held under insanitary conditions. A mass seizure in Chicago included fresh frozen shrimp with rodent remains on its carton, while another Chicago mass seizure found frozen File Fish, Dried Squid and frozen salted shrimp to be contaminated with rodent excreta pellets. A Baltimore mass seizure found schrod, cod, and clam chowder to have rodent excreta pellets on their packaging. A seizure was completed in Alabama for cooked crab prepared, packed and held under insantiary conditions.

FISH FROM ALASKA

Mr. Akaka. What has been your experience over the past year with fish coming out of Alaska, particularly in the areas polluted by the Exxon VALDEZ? Have you been monitoring this closely?

Mr. Benson. In response to the Exxon vessel Valdez crude oil spill, the Alaska Department of Environmental Conservation requested assistance from FDA to inspect the seafood processors throughout Alaska to assure the American public that the seafood products were not contaminated with oil, and FDA responded. Although no evidence of crude oil was found on the seafood products in 1989, the Alaska Department of Environmental Conservation has requested FDA assistance in 1990 for several reasons: First, to provide continued surveillance of the fisheries both to protect the public health and since it represents a multi-billion dollar industry. Any perception by the American public of a reduction in the surveillance activities by the regulatory agencies could have a devastating affect on the industry and a significant impact on Alaska's economy. Second, it is anticipated that the entire Kodiak and Cook Inlet fishing areas will be opened in 1990. These areas were heavily impacted by the oil spill and many major processors located in those areas will require inspection. Coverage above the 1989 levels will be needed in those areas. Third, the Alaska Department of Environmental Conservation has lost experienced seafood inspectors since the 1989 salmon season and they are relying upon FDA to fill the void and to provide training to the new personnel they plan to hire for the 1990 halibut and salmon seasons.

NUTRITION LABELING

Mr. Akaka. Are you confident that your recent proposal to expand and revise labeling on retail foods will clear up consumer confusion about the nutritional components of foods?

Mr. BENSON. On March 7, 1990, the Secretary of the Department of Health and Human Services, Dr. Louis W. Sullivan, announced a series of major changes FDA will propose for food labels to provide better information for consumers and make it easier to obtain sound information on the nutritional value of foods. These changes which have yet to be proposed but will be in the near future, will include mandatory and consistent nutrition labeling requirements for most foods, standardization in key factors including serving size and descriptions like low fat and high fiber, as well as revised contents for the food label itself. The food label is recognized as an important source of nutrition information for the consumer, and the revisions to be proposed will reflect the latest scientific knowledge about diet and health. The ultimate goal for this activity is to provide readily useable information on as many foods as possible so that the American consumer can more easily follow guidelines that relate diet with the maintenance of good health. When these actions are completed, we believe that we will have eliminated most, if not all, consumer confusion about the nutritional content of foods.

Mr. AKAKA. What about health claims? Are you confident that your proposal will prevent inappropriate health claims that appear on packaged foods?

Mr. BENSON. In the Federal Register of February 13, 1990, FDA reproposed to amend the food labeling regulations to provide for the use of health messages on food labeling. The purpose for the reproposal is to attempt to establish procedures for permitting valid and reliable consumer information on food labels about the value that ingestion of a dietary component, as part of a total dietary pattern, may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease condition. FDA has also outlined how it is likely to enforce its regulations that bear on health messages during the period that it is receiving and considering comments on the reproposal. FDA is confident that the reproposal clearly enunciates the criteria it proposes to use to determine whether a health message or health claim is inappropriate. If deemed inappropriate, FDA has also discussed its compliance policy to indicate that health messages on foods that are inappropriate would be subject to regulatory action under the reproposed rule.

Mr. AKAKA. What kinds of health claims will still be permitted?

Mr. BENSON. The reproposed rule on health messages of February 13, 1990, identified potential topic areas about which significant evidence and general scientific agreement exists to support a health message about the relationship between intake of a dietary component reducing the risk, or delaying the onset, of a particular chronic disease condition. Six topic areas were identified and the reproprosed rule asked for comment on these or any others for which health messages may be appropriate. Until all comments are received and analyzed, and a final rule adopted, it is difficult to respond as to exactly what types of health claims, if any, will still be permitted. Accordingly, a direct answer to the question cannot be made until the rulemaking is complete.

Mr. AKAKA. Thank you very much. I really appreciate your responses.

Mr. **Whitten**. Mr. Smith?

SEAFOOD INSPECTION

Mr. **Smith**. Following up on this, you said that you inspect one-fourth of the processors and you inspected a large number of imports, but what percentage of the seafood imports did you inspect?

Mr. **Benson**. Let me check with the records here. It is in the vicinity of somewhat less than 10 percent.

Mr. **Smith**. Not only less than 10 percent; it was 1 percent, wasn't it?

Mr. **Benson**. Well, I think it is more than 1 percent. It would be certainly——

Mr. **Smith**. I understand it was 1 percent, and 3 percent of domestic production. The other way around. Three percent of imports and 1 percent of domestic.

Mr. **Benson**. I'm not sure of the numbers, but I think the foreign level was greater than domestic.

Mr. **Smith**. Right. But it was virtually none.

Mr. **Benson**. No. I wouldn't say virtually none.

Mr. **Smith**. You don't think 3 percent is virtually none?

Mr. **Benson**. No, I do not—especially recognizing that that is a targeted percentage in terms of really zeroing in on where we expect to find problems. It is not supposed to be a random sample.

Mr. **Smith**. Well, in poultry and meat inspection you might as well not have any inspection if you are only going to inspect 3 percent.

We have a voluntary program which is enrolled in primarily by those who want to use it as a method of promoting sales. I believe 10 percent or something like that is enrolled in that program.

What you are proposing in your proposal really is just to increase the volume that is under voluntary programs. Isn't that essentially correct?

Mr. **Benson**. No. What we are proposing is to do more—to follow up on your point—increase both domestic, and especially foreign inspections to get those percentages up. I think that should be done. That will be done under the proposal.

As far as the voluntary inspections that you talked about, that whole program is more than an opportunity for the industry to market. It is an opportunity to really put together a strong quality control program, both from the standpoint of safety as well as from the standpoint of quality of product. So they will have a mark of approval there that will demonstrate that they do meet certain standards. It is based on a program that really started in the NASA area. Pillsbury Food Company picked it up in terms of really looking at the weak points in a processing system. Now it is being applied to seafood.

We have already done, in association with National Marine Fisheries, a number of workshops with the industry explaining how that works.

Mr. **Smith**. It just stands to reason, doesn't it, that the ones that want to enter into voluntary programs are the ones that need it the least?

Mr. **Benson**. Yes. I think that follows.

Mr. SMITH. So a voluntary program is not going to do you much good, as I can see it. The ones we really need to inspect are not going to be in a voluntary program.

Mr. BENSON. I think that there is no question in my mind that a mandatory program across the board would be superior. I won't argue that.

Mr. SMITH. It would be what?

Mr. BENSON. Superior.

[CLERK'S NOTE. Subsequent to the hearing, the FDA reported that six percent of the 1989 import entries of seafood were inspected.]

Mr. SMITH. Yes. Did I understood you to say the seafood that we are eating now is safe and wholesome? I am interested in that word "wholesome." I was the author of the Wholesome Meat Act and the Wholesome Poultry Act. Wholesome, as it is defined in that law—which was an amendment to your law, even though it is administered by the Department of Agriculture—means it is handled in a manner—it is not just micro-biologically safe, but it is handled in a manner that you'd think it was, if you watched it from the beginning to the end, that you wouldn't mind eating the product. Is that the way you are using wholesome?

Mr. BENSON. Yes. In essence, that is right—to make sure that it is high quality, that it is what it purports to be, that there is not substitution of shark for mussels and that kind of thing.

Mr. SMITH. Not handled under unsanitary conditions?

Mr. BENSON. Well, you are bordering on safety now, but certainly that, too.

Mr. SMITH. I am not emphasizing safety now, I am emphasizing wholesomeness.

Mr. BENSON. Yes, I would say so.

Mr. SMITH. Well, am I mistaken then? All the reports I have heard say that many, many of these seafood products are handled under very unsanitary conditions. That doesn't mean that it won't be safe to eat, but if you knew how it was being handled you wouldn't want to eat it. Is that not true?

Mr. BENSON. I have heard the same thing about some other products, but——

Mr. SMITH. It might be true, too.

Mr. BENSON. I don't have—I am not aware of a large body or any poor sanitary conditions for processing of seafood. I think that if we felt there were we would be in there trying to correct the situation.

Mr. SMITH. Well, some of it is not just processing; it is before the processor gets it.

Mr. BENSON. That may be in terms of coming off the catch boats and things of that sort.

Mr. SMITH. Correct. And the way they handle it on the boats.

Mr. BENSON. I think, in my view, part of that HACCP program ought to include really making sure that refrigeration and those kinds of things happen on the boats, as well as once it hits the shore.

SHELLFISH

Mr. SMITH. Now, you said what we need to do is take the sewage out of the water. Well, that sounds good, but, as I understand it, the only place in the United States that oysters don't feed in waters that are contaminated by sewage is the mouth of the Appalachicola River. All other places where we have oyster beds have access to sewage. Is that right?

Mr. BENSON. I don't have the statistics on that. I'd be glad to get them for you if you would like it for the record. But my feeling is that there needs to be standards in place—and there are standards in place—that once the raw sewage level, or whatever contaminant level, reaches a certain point, then harvesting would have to cease in those areas. That is the way the program is being administered now.

The problem is that the raw sewage is too great, so it would be——

Mr. SMITH. The point I want to make is that I don't see any possibility in the foreseeable future of eliminating all the sewage from all these places where they feed. I don't think that is a practical approach to use at all.

Mr. BENSON. I agree.

Mr. SMITH. So, in the meantime, one thing that might help would be to provide more effective warnings of the dangers of eating raw oysters.

Mr. BENSON. I agree with you. I think that is something that——

Mr. SMITH. Is there a way you can have——

Mr. BENSON. Yes.

Mr. SMITH [continuing]. Have more warnings not to eat raw oysters?

Mr. BENSON. I think that it is important that people understand the level of risk and what the risk is they are exposing themselves to when they eat raw shellfish. I think that——

Mr. SMITH. Is it all shellfish or are oysters worse than other shellfish?

Mr. BENSON. I think we're talking about oysters and——

Mr. SMITH. Raw.

Mr. BENSON. Raw oysters or raw clams, raw mussels, things of that sort.

Mr. SMITH. Things where you are eating the stomach and all.

Mr. BENSON. Exactly. We do a pretty good job of warning people not to eat raw poultry or raw beef in most cases.

Mr. SMITH. Right.

Mr. BENSON. And we should do the same thing I think with raw shellfish—especially until we can overcome those problems. And if we never can overcome them, then we ought to warn people to not eat them.

Mr. SMITH. Other than hepatitis, what are some of the diseases associated with eating raw oysters?

Mr. BENSON. Doug, do you want to—I'll have Dr. Archer answer your question on that. He is the expert.

Mr. SMITH. All right.

Dr. ARCHER. Thank you.

The main disease associated with raw oyster consumption is viral gastroenteritis, caused by a virus called the Norwalk agent. I am not aware of any reports of lethality associated with that particular organism. It is a very short, acute, self-limiting, diarrheal episode.

In seriousness, there are a list of marine vibrios in the genus vibrio bacteria related to the cholera bacteria, but the difference is that they are free-living in ocean water. They are not associated with sewage or human waste. These pose a special health hazard to people with certain underlying illnesses such as cirrhosis. We have gone to some rather extreme lengths to warn physicians and people with cirrhosis not to consume raw oysters. In those persons, if they contract one of these diseases, it has a mortality rate of approximately 50 percent, so it is a very serious condition.

There are about 16 different organisms associated with raw oysters that can cause acute self-limiting disease.

Mr. SMITH. I know the statistics would be very, very incomplete, but are there any statistics on how many people become seriously ill or die from these diseases?

Dr. ARCHER. The estimates that we have made are that there are about 60,000 episodes of illness a year associated with the consumption of raw oysters and about 20 deaths. All of those deaths virtually are associated with the consumption of raw oysters by persons with cirrhosis or other liver disease.

Mr. SMITH. Now, in the case of hepatitis—and I happen to know a couple of people that got hepatitis from raw oysters out of the Chesapeake Bay—that usually doesn't cause death. Is that so or not?

Dr. ARCHER. It has got a mortality rate between 2 and 5 percent—hepatitis A.

Mr. SMITH. I see. But it can cause some very serious illness for a long time.

Dr. ARCHER. Very debilitating disease.

TREATMENT OF RAW OYSTERS

Mr. SMITH. Well, is there any way to treat raw oysters—I'm using oysters as an example, but you know what I mean—so that it is safer without affecting the taste?

Dr. ARCHER. There are many experiments now. The agency is involved in some of these pilot studies with a process called depuration where the shellfish are put into water that has been filter-purified or otherwise disinfected. Essentially it is a self-cleaning process. The oysters are allowed to pump through a lot of clean water.

It is very effective with some of the pathogenic organisms, and yet there are some that are still a problem even after the depuration process.

Mr. SMITH. What about irradiation?

Dr. ARCHER. The irradiation would be effective; unfortunately, it is not that generally acceptable at this time. We have done studies with the irradiation of shellfish, and it does work.

Mr. SMITH. It works well for other meats and this is why I wondered if it would also apply to shellfish. We are virtually ready for marketing a small low-cost irradiation chamber that you could pass packages through. Would that work with shellfish the way it will with poultry and——

Dr. ARCHER. Yes, it would. Slightly higher doses of irradiation would have to be used to destroy the viruses.

Mr. SMITH. I see. And would it affect the taste, or do you know?

Dr. ARCHER. It should not.

Mr. SMITH. Should not affect the taste? And they could properly label the package to indicate that the product was processed by irradiation. If they don't like irradiation, buy a package that doesn't have it on it. But you would put on the package a label that indicated that it had been irradiated. Is there a more practical way to handle this problem than that right now?

Mr. BENSON. Not that I am aware of.

Mr. SMITH. Have you done any work on this?

Mr. BENSON. Doing a more sophisticated job of identifying polluted waters and preventing harvesting from those waters is the alternate to correcting the problem the way we were talking about.

Mr. SMITH. Well, if you prevent harvesting from polluted waters there won't be any seafood. Of course that would eliminate the problem, there won't be any seafood.

Mr. BENSON. I agree. I was just exploring the options. I think there is a good supply of seafood from waters that are relatively safe—that is, that would not cause problems now.

VOLUNTARY SEAFOOD INSPECTION

Mr. SMITH. This proposal you have made regarding seafood inspection is similar to one made by the Commerce Department. Did that originate in your shop? Where did that proposal originate?

Mr. BENSON. We have worked a number of years with National Marine Fisheries. The HACCP program, itself, is something that is growing. I think presently they have a contract with the National Academy of Sciences to look at how HACCP would be applied. So if you are talking about the HACCP program specifically and sort of go back in history, I think the most recent event is a contract from National Marine Fisheries.

Mr. SMITH. Yes.

Mr. BENSON. In terms of where the program ultimately originated I think it came out of the aerospace industry.

Mr. SMITH. No. What I am really referring to is the proposal that our answer to the seafood problem is merely to expand the voluntary program. Where did that policy come from?

Mr. BENSON. I understand your question. For the last one or two years we have been trying to work with National Marine Fisheries for an improved program based on existing law, so I think that is mutual.

Mr. SMITH. Who made the decision that that was the approach you should take in looking for a solution?

Mr. BENSON. I don't think it was them any more than us. I think it was a joint decision.

Mr. SMITH. I see.

Mr. BENSON. And it was confirmed by the Administration in the 1991 budget where they enhanced the mandatory program by $9 million and suggested that we do more in the voluntary area, as well.

FDA'S SEAFOOD CAPABILITIES

Mr. SMITH. Now, when I first drafted the Meat and Poultry Inspection Acts, I thought long and hard about where it should be administered. Advice that I was given at the time—I had only been here a few years at the time was that FDA has so many responsibilities in highly technical areas that you shouldn't bog them down with a day-to-day inspection program that is going to require thousands of people to administer. Was that not a right judgment, or is that still true?

Mr. BENSON. It boggles my mind to think about having a program with literally thousands of inspectors. We have under 1,000 inspectors right now——

Mr. SMITH. Right.

Mr. BENSON [continuing]. To do all the work that we are presently doing.

My own belief is that the seafood program integrates well in a number of areas—from a scientific standpoint in terms of some of the research that we are doing, in terms of identifying probes and so on to pick up——

Mr. SMITH. And you would still need to do that.

Mr. BENSON. Absolutely.

Mr. SMITH. Yes.

Mr. BENSON. I think that one of the things that is very exciting to me personally is the integration and the synergy we get from working with the States. I think this is a growing area. We do it in the milk area. We do it in the radiation control area—which is a program that I came from. That is why I am particularly familiar with it—and retail store areas. It is very much an integrated program with the States, as I believe the seafood program should be.

Presently we have a high degree of cooperation in the shellfish area with the States with the shellfish cooperative program.

I think the synergy that exists in a number of areas is one that enhances FDA and FDA does well with.

Mr. SMITH. The long and short of it is, if I read between the lines, that it is still true and that you would agree, if you are pressed to do so, that if you are going to have what I would call an adequate program that involves at least hundreds, if not thousands, of people involved in concentrating on not only microbiological problems but also wholesomeness problems that really doesn't fit your agency? Without picking out an agency to do it, that is really not the kind of an assignment you ought to have?

Mr. BENSON. With due respect, sir, no, I wouldn't agree to that if pressed. I have always been very candid in these sessions—in any hearing.

I think it is a function of what is the best way to operate the program. I personally think that a very solid seafood safety and wholesomeness or quality program can be run without the thousands of——

Mr. SMITH. But I'm saying suppose we require a program involving a substantial number of inspectors—some highly skilled and some less highly skilled—to operate it, to make observations, and so on and so forth, including the substantial administrative problems involved? Assuming that, should FDA have it or somebody else?

Mr. BENSON. FDA has 21 district offices. We have well over 100 additional resident posts scattered around the country——

Mr. **Smith**. Do you think you could handle the meat inspection program if it was assigned to you very easily?

Mr. **Benson**. I would want to have a lot of time to gear up for that if that happened in terms of making sure we understood what the program was supposed to do and how to operate it. But yes, I certainly do think we could handle it. We have operated a field program for virtually all of this century.

Mr. **Smith**. But nowhere near the magnitude of what I am talking about in administrative problems.

Mr. **Benson**. I think in terms of magnitude no, not near what you are talking about.

Mr. **Smith**. That's all I have. Thank you.

Mr. **Whitten**. Mr. Skeen.

FDA'S INSPECTION FORCE

Mr. **Skeen**. The FDA has come under increasing criticism for not having the resources needed to adequately inspect the tremendous amount of food that is imported into this country. We have a serious enough problem with the public perception about the food we produce domestically. We need to ensure that the public's confidence remains high in all food products that are on our grocery shelves. In light of this, I am puzzled at FDA's request for an increase in personnel for inspections.

Does FDA believe an increase of 125 personnel will provide it with the adequate level of resources needed to inspect imported food items?

Mr. **Benson**. It is difficult to define what is adequate, but we believe that this additional 125 FTE requested for this purpose allows us to begin the process of rebuilding and restoring our field operations in a reasonable way. At present we are covering about eight to ten percent of the formal entries, $1250 or higher, of imported food products coming into the U.S. annually. For this level of coverage we are devoting about 580 FTEs.

Mr. **Skeen**. What specific activities will these additional 125 personnel be involved in? Can you give me an idea of the increase we will see in inspections?

Mr. **Benson**. The 125 FTEs requested for restoration of field capabilities are projected as follows: 75 positions for Foods; 25 positions for Human Drugs; 13 positions for Medical Devices and Radiological Health; and 12 positions for Animal Drugs and Feeds. With the 75 positions for food restoration work, 35 FTEs will be resources devoted to domestic work to increase the number of inspections by about 1000. The remaining 40 FTEs projected for coverage of food imports will provide for the collection/analysis of 2500 additional samples.

Mr. **Skeen**. What assurances can you give this committee and the public that your request for personnel will allow you to adequately protect the public?

Mr. **Benson**. FDA takes its consumer protection mandate seriously. We believe that, with the increases requested in this budget, FDA can begin to rebuild its field force in a way that allows us to increase the level of protection we provide to the American public. There is no fixed number above which I can say that the level of public protection is adequate. Adequacy of protection is a judgment that involves balancing the research available with skillful management of those resources. We believe that the request in the President's budget allows us to move in a reasonable way toward restoring our field resources in 1991, but certainly no absolute assurances of adequacy can be given.

Mr. **Skeen**. Will this budget request for inspectors allow FDA to carry out its mission of inspecting imported food items and respond to an emergency that may develop during the next year?

Mr. **Benson**. The budget increase requested will restore some of our capability so we can increase our monitoring of imported foods. We will continue to respond to emergencies by diverting resources from lower priority work if necessary.

Mr. **Skeen**. Have you prioritized the type of food products that should be inspected by FDA?

Mr. **Benson**. Yes. Foods susceptible to microbiological contamination, closely followed by those with possible industrial chemical or pesticide contamination, are our top priority. Mycotoxins and food additives are next, followed by economic fraud.

RESEARCH ON TOXIC SUBSTANCES

Mr. **Skeen**. I was fascinated to read last month the statement by an FDA official regarding the cancer risk present in the foods we consume. The information presented indicated that 98% of the cancer risk come from naturally occurring toxins. Dr. Frank Young stated that this information shows we need to focus on the big picture of the cancer risk in our food supply. Does the proposed FDA budget allow you to look at the big picture?

Mr. **Benson**. No single agency is big enough to address adequately the whole of the big picture of the cancer risk in our food supply. FDA, NIH, EPA, universities, and other scientific institutions need to play a role—a larger role than they currently do. Over seven years ago, the Center for Foods recognized the need for work in the area of dietary cancer risk and established a Nutrition/Toxicology Program in an effort to combine its resources to conduct studies in this area. The program is expected to be long-term.

Mr. **Skeen**. What research is currently being conducted by FDA on identifying naturally occurring toxins in our food supply?

Mr. **Benson**. For several years, FDA has conducted chemical and biological development work on better methods of isolating, identifying, and measuring the levels of several important food-borne toxicants.

We have pioneered the analysis of aflatoxin and its metabolites and continue to develop cheaper and more sensitive detection methods for detection and monitoring. Our capability to reliably detect aflatoxin in food has increased from 20 ppb in the 1970's to approximately 1.0 ppb in recent years.

Shellfish occasionally contain potent natural toxins that can cause serious, and sometimes even fatal, poisonings in humans. These toxins are classified in terms of the symptoms they produce, such as paralytic, neurotoxic, amnesic, and diarreahetic shellfish toxins. Our scientists have been investigating the identity, nature, and incidence of these seafood toxins and pursuing the development of reliable regulatory detection methods.

Changes in spoilage patterns in canned tuna and other fishery products require the reevaluation of traditional decomposition indicators and the application of new decomposition indicators.

Laboratory studies of natural foodstuffs have revealed a diverse armamentarium of natural toxicants including mutagens, carcinogens, antinutrients, and other toxins with acute or chronic adverse effects. These substances have apparently developed as defense mechanisms to insure the survival of plant species against the depredations of animal and microbial predators. The presence of these substances in traditional food occasionally raises the immediate question of the safety of the food when consumed by man, for example, solanine in potatoes, oxalic acid in rhubarb. But more importantly, these substances may contribute in yet unappreciated ways to our burden of chronic dietary risk. It is important to develop a data base containing information on the incidence of levels of such toxins in foods and feeds. Our projects in this area include a survey of commercially available comfrey samples for pyrrolizidine alkaloids; a collaborative study for HPLC determination of agartine in mushrooms; and a screen of commercially available edible fungi, mushrooms, for the carcinogens agartine and gyromitrin. In addition, FDA is developing a computer based information data base to catalogue the identity and quantity of natural carcinogens in our food supply. This information, together with data on the consumption of the identified foods, will enable us to better estimate the potential risk. There are six phases in the project. First, we will identify and classify all plants, animals, and minerals used as food. Second, we will identify all naturally occurring chemicals which can cause cancer. Third, we will determine the concentration of each carcinogen in each food. Fourth, we plan to calculate the amount of each type of food eaten. Fifth, we intend to estimate the total quantity of each carcinogen eaten. Sixth, we will estimate the risk of cancer for the population.

FDA is collaborating with NCI on a project to determine the feasibility of adding anticarcinogens to the diet. FDA will be conducting safety studies on known anticarcinogen containing substances as a preliminary to subsequent planned clinical trials to be conducted by NCI.

RISK ASSESSMENT

Mr. SKEEN. I note that FDA wants to improve its current risk assessment procedures and techniques. What do you propose to do in improving your work in this area?

Mr. BENSON. The major food risk assessment activities of FDA are located at the National Center for Toxicological Research, and at the Center for Food Safety and Applied Nutrition. Both Centers are committed to improving risk assessment methods and to reducing the uncertainty inherent in current procedures. Work is proceeding or proposed in exposure assessment, dose-response methodology, and high-to-low dose and animal-to-human extrapolation.

FDA's research efforts aimed at improving risk assessment have a broad reach. For example, NCTR is conducting a large-scale study on the impact of dietary restriction, such as fewer calories, on the incidence of cancer in rodents. It is now quite clear that leaner animals get fewer tumors when exposed to the same level of carcinogen. Currently our animal-based risk assessment models ignore the effect of the animal diet.

NCTR and Foods are also developing new means of assessing the risk from exposure to neurotoxins. This area has been relatively neglected in the past. NCTR is also attempting to redirect some of its efforts toward the reproductive and developmental areas.

NCTR is also developing procedures for measuring exposures to carcinogens by means of sensitive DNA and protein markers. These markers should help improve our knowledge of the extent, time, and severity of exposures to carcinogens and other toxicants.

Foods is also planning a major program aimed at improving cancer risk assessments based on rodent bioassays. Projects will include the development of dosing regimens that more accurately reflect human use; development of methods to more accurately determine tissue and organ doses in animals; and development of physiologically-based pharmacokinetic models to allow more reliable animal-to-human extrapolation.

Mr. **Skeen**. Do you think we are lacking in our ability to communicate accurate information to the consumer the level of risk found in our food supply?

Mr. **Benson**. Generally, yes, for several reasons. The largest risk from our food supply is traditionally accepted without complaint, chronic rather than acute, and generally within the control of the individual. This is the risk from the diet itself. There is reasonably good consensus that approximately a third of all cancer risk is diet-related. Similar percentages for arterial disease, diabetes, and other chronic effects are widely known and accepted. By comparison, the risk of the single chemicals like pesticides, artificial sweetners, and colors are small. Yet these chemicals get the agency, congressional and media attention despite their much lower risk.

Second, current methods for assessing cancer risk in particular are still inadequate and rely heavily on uncertain extrapolation procedures. To bridge this uncertainty and to ensure that any questions are resolved in favor of the public health, our current methods are intentionally conservative. It is difficult to get the public to understand that our risk assessments are protective and not predictive of actual human harm.

Mr. **Skeen**. Thank you.

DELANEY CLAUSE

Mr. **Whitten**. Getting back to some things that bother me. When the Secretary of HHS issued an order banning the use of red No. 3, he went out of his way to say that the actual risk was extremely small, however, federal law was clear. If there is no such thing as zero, then everybody is operating by sufferance. His view was that he couldn't do anything except stop it. Well, if we were to follow that course of action, we would all starve to death.

Are you making any effort to change the Delaney Amendments? Or are you deciding that—and this is a show of danger—as long as the Delaney clause remains the law you are letting everybody operate by sufferance?

Are we just going to continue and allow those in business to suffer at the sufferance case or count on you looking the other way if you have to. What is the solution?

Mr. **Benson**. I don't think it is proper for us to look the other way, but Dr. Sullivan and——

Mr. **Whitten**. Dr. Sullivan is a very fine Secretary in my opinion and a fine man, but he went out of his way to point out there is little risk, but it was the only decision he could make. I don't agree with him on that, but that is what he said.

Mr. **Benson**. What he said last week—in announcing our labelling initiative, he also talked about the Delaney Clause and the need to have it altered. So to me that announces the Department's intent to do exactly what you are suggesting— get on with changes.

Mr. **Whitten**. Well, good intentions are easy to come by. It is the effectiveness of doing something about it that I am asking about.

Mr. **Benson**. The effectiveness of doing something about it requires us convincing the Congress that it needs to make the change, and that is not an easy task.

Mr. **Whitten**. Well, I have tried to get it changed three or four different times. Mr. Delaney agreed at one time with me and as long as we would keep his name on the Amendment he would go along with modernizing the rules, but I never could get it going.

Mr. **Benson**. Maybe we can form a partnership and get on with it. I'd be for that.

Mr. **Whitten**. Thank you for your appearance here. You do a great job by and large—and you have got a tremendous job to do. We do appreciate it.

Mr. **Benson**. Thank you very much, sir. I appreciate those words.

Mr. **Whitten**. Mr. Traxler, Mrs. Smith, and Mr. Conte were unable to be here today. They have some questions they'd like answered for the record.

[The questions and responses follow:]

ANSAID APPROVAL

Mr. **Traxler**. I understand that the Food and Drug Administration had difficulties in completing the approval process for Ansaid, an anti-inflamatory drug produced by the Upjohn Company. The application was submitted to FDA in March of 1982, but was not finally approved until 1988 following a 79 month review period. Is it true that at the time Upjohn submitted its application that FDA was able to approve nonsteroidal anti-inflammatory drugs in an average time of 26 months?

Response. Prior to 1982, review of applications for nonsteroidal anti-inflammatory drugs averaged 26 months. Since that time, however, the average review time for approval increased for all these drugs.

Mr. **Traxler**. You say that the average time for reviewing anti-inflammatory drugs has increased from 26 months. How much has it increased?

Response. The average review time for nine non-steroidal anti-inflammatory drugs approved from 1983 through 1989 was 59.4 months.

Mr. **Traxler**. What caused the delay in your approval of this drug?

Response. It was a matter of priorities. The anti-inflammatory drug review group was involved in the review of several other important drugs which had a higher review priority.

Mr. **Traxler**. To the extent that the delay in approval was due to other demands on your resources, why didn't FDA request additional resources?

Response. For some time we have regarded the need for additional resources for the drug review process as a high priority request in view of the growth in the number and complexity of drug applications submitted for approval. In the past several years, we have requested and received several increases for new drug review.

Mr. **Traxler**. Upjohn had a right to expect an exclusive marketing period based on the time that it was able to market the drug following your approval. To the extent that you were unable to approve the substance in a timely manner for reasons beyond the control of Upjohn, isn't it true that Upjohn was materially injured in having lost the right to as substantial an exclusive marketing period as it might have reasonably expected when it submitted its application for Ansaid?

Response. FDA is not in a position to comment on whether Upjohn was "materially injured" by the length of review of its NDA for Ansaid. I should note, however, that Upjohn has the option to petition the U.S. Patent Office directly for patent extension for a period reflecting the length of testing and FDA review of Ansaid, pursuant to The Drug Price Competition and Patent Term Restoration Act of 1984.

Mr. **Traxler**. The Drug Price Competition and Patent Term Restoration Act of 1984 provides companies with a limited period of relief for products delayed in the normal drug review process. In the case of Ansaid, Upjohn obtained a 24 month patent extension for only a small portion of the 79 month review period. Does the FDA or any other agency have a mechanism where a company like Upjohn could get additional market exclusivity to compensate for an unusually long review time—54 months in this case—not covered by the patent extension law?

Response. FDA is not aware of any other such mechanism.

FOOD LABELING

Mr. **Traxler**. Recently it was announced that you will undertake a major food labeling standardization effort. Could you fully describe exactly what it is you will be doing, and your time schedule?

Response. On March 7, 1990, the Secretary of the Department of Health and Human Services, Dr. Louis W. Sullivan, announced a series of major changes that FDA will propose for food labels to provide better information for consumers and update label information so that the latest scientific information on diet and health is reflected. A document from FDA titled "Food Label Reform" and dated March 7, 1990, provides detailed information on this initiative to revise the food label and also gives a timetable for the three phases within which the various concepts for labeling reform will be developed.

[CLERK'S NOTE.—The report is too lengthy for reprint. A copy has been retained in committee files.]

Mr. **Traxler**. Some people are concerned that food labels can be misleading when providing percentage content information. For example, if a particular food component should be no more than 30% of a person's daily diet, the person will reject any food product in which the component exceeds the recommended percentage. As a result, people could be losing out on actually obtaining the recommended daily component by eating those foods either at or below the recommendation as opposed to eating a variety of foods that when combined result in the recommended percentage components. What is your view of this matter?

Response. The points at issue appears to be concern for misinterpretation of recommendations that deal with guidelines for the macronutrient, for example, protein, carbohydrate, and fat, and energy content of a well-balanced daily diet. A most recent example of such a recommendation is one of several from the National Research Council in its book "Diet and Health: Implications for Reducing Chronic Disease Risk" that provides the rationale for American consumers to reduce the daily dietary total fat intake to 30 percent of calories. It is conceivable that this may be misunderstood to mean that any single food which drives more than 30 percent of calories from fat should be excluded from a diet. This, however, is not the intended effect for which the recommendation was made. Presently under FDA regulations, the nutrition information panel does not present the fat content of a food as a percentage of calories or anything else. It is merely presented as an amount in grams per serving.

The FDA document "Food Labeling Reform" of March 7, 1990, presents alternative formats for declaration of nutrition information. Some of these formats would present, or are amenable to presenting, macronutrients in amounts by weight as well as percent. These and other formats will be explored, subjected to public comment, and possibly developed for use in a revised format. This activity will certainly include a major effort in consumer education so as to preclude any misunderstanding of nutrition information and consequent misuse of a product.

Mr. **Traxler**. There has been great confusion about nutrition information. We all just experienced the oat bran situation in which nutritional claims were found to be exaggerated. How can you guard against similar problems in your food labeling efforts?

Response. This issue more directly concerns health claims in food labeling rather than nutrition information, which lists the nutrient composition of a food product. FDA issued a proposed rule on health messages on August 4, 1987, that dealt with claims for foods regarding the association between certain nutrients or foods constituents and the maintenance of good health or the avoidance of several chronic diseases. In time, FDA came to the conclusion that the proposal was too broadly written. In a few extreme cases, some manufacturers took advantage of uncertainties created by the proposal by making drug claims on health fraud products and then, when challenged by FDA, asserting that the claims were consistent with the August 4th proposal. Other lesser problems also occurred. To correct this situation, FDA withdrew the August 4, 1987 proposal in its entirety and reproposed a narrower rule on February 13, 1990. For the period when comments on the proposal are being received and considered, FDA also announced an interim enforement policy regarding the possibilty of regulatory action for a health message that is inconsistent with the preproposed rule.

Mr. **Traxler**. By statute, USDA is the lead agency on human nutrition. How will you coordinate your efforts with the Department, particularly with the Food Safety and Inspection Service and the Human Nutrition Information Service?

Response. The FDA document of March 7, 1990 titled "Food Labeling Reform" indicates that FDA will harmonize the reform activities and make its food labeling requirements as consistent as possible with those of the Department of Agriculture to insure consistency with USDA's regulatory requirements for labeling of meat and poultry. In the public meetings on food labeling that FDA held at four locations across the country in November and December of 1989, a representative from the Food Safety and Inspection Service was included as a panelist along with representatives from FDA and the Department of Health and Human Services. To the extent possible, FDA has met with key personnel in USDA prior to publication of food labeling reform proposals to provide them with a general indication of the substance of the proposal in order to maximize coordination between the two organizations. Moreover, DHHS and USDA have jointly constructed with the National Academy of Sciences for a report on food labeling that is due in September. Activities of this nature will continue until all proposals are publicly announced.

Mr. **Traxler**. FDA does not have a research role. How will you coordinate with the Human Nutrition Research laboratories operated by the Agricultrual Research Service and other human research efforts conducted by the Cooperative State Research Service?

Response. FDA does have a research role and has been very active in those areas of human nutrition that pertain directly to FDA's mission in food safety and applied nutrition through the maintenance or improvement of the nutritional quality and labeling of the U.S. food supply. FDA actively coordinates its efforts with USDA components as it also does with the National Institutes of Health, the National Center for Health Statistics, the Centers for Disease Control and other components in the U.S. Public Health Service that conduct basic or applied research in public health and human nutrition.

Mrs. **Smith**. Currently food labeling and nutrition information have become important consumer concerns. As we are all aware, many Americans are very interested in additional nutritional information about the food they purchase. However, controversy regarding a program established by the American Heart Association (AHA) named "Heart Guide" has developed. The AHA is offering for a fee to review and then label foods they find appropriate.

I am aware that the FDA has taken action in agreeing with the USDA that the Heart Guide program should *not* be pursued by private individuals.

Commissioner Benson, would you comment on this situation, In addition, would you update the committee on the actions being taken by the Heart Association regarding "Heart Guide?"

Response. The Agency has informed the American Heart Association (AHA) that inclusion of the AHA Heart Guide seal on the label of a food may run the risk of misbranding that food. The agency pointed out that the seal could be misleading since the consumer is not informed that the presence of the seal was made possible by payment of a fee; the presence of a seal would imply that the food is low in fat, saturated fat, cholesterol and sodium when in some instances the levels of these substances would be above FDA regulatory definitions; and it was not made clear that the criteria used for product acceptance pertain to normal healthy adults and may not be useful for individuals on retrictive diets. In addition, third party endorsement programs often result in the creation of the appearance of a good food, those with endorsement, versus bad food, those without endorsement, situation. The FDA believes that the total diet, and not only specific individual foods, is the main concern in improving health.

We are continuing to have discussions with the AHA at their request in an effort to resolve the issues cited above.

[Clerk's note.—Subsequent to the hearing, on April 2, 1990 the AHA announced its intention to withdraw the Heart Guide program.]

Seafood Inspection

Mrs. Smith. I am aware after reveiwing the FDA budget proposals that the agency is seeking a $9 million increase in the agency's spending for seafood inspection. Currently, the FDA inspects mostly imported seafood.

Many proposals regarding a comprehensive seafood inspection system are being circulated around Capitol Hill at this time. However, controversy has developed on whether a seafood inspection system should be located in the FDA or the USDA.

Commissioner Benson, would you comment on this situation? Has the FDA been working with the USDA to resolve this controversy?

Response. FDA has a total seafood safety program in place which addresses both import and domestic products. The following chart shows our recent yearly efforts for seafood safety assurance, including inspections, sample analyses and other work.

	FTE's	Millions
Domestic seafood inspections/analyses	84	$6.8
Import exams/analyses	103	8.5
Liaison with States	24	2.0
Research	55	5.0
Compliance and National Shellfish Sanitation Program	26	2.1
Education/information	8	.6
Total seafood expenditures	300	25.0

FDA is also aware that a number of different proposals regarding seafood inspection have surfaced in the past few months. After meetings that included FDA and USDA, the Administration has decided that the seafood program will remain with FDA and the National Marine and Fisheries Services. USDA officials have been present at Administration meetings where this conclusion was reached.

FDA and the National Marine and Fisheries Service are in the process of developing a joint enhanced voluntary fee-for-service inspection program which will be based on HACCP principles. This voluntary program will be in addition to FDA's mandatory inspection program. In addition, FDA's 1991 request includes an increase of $9 million to enhance the agency's present applied research and surveillance activities related to seafood.

Food Safety

Mrs. Smith. Included in the President's budget proposal for FY91 is an increase of $3 million for food safety research and consumer assurance programs. Commissioner Benson, as you are aware, the President's budget for FY91 includes a $118.2 million request for Food Safety Programs.

Would you briefly explain to the committee the total amount of funding the FDA is putting forward in FY91 for food safety programs? In addition, why is the FDA food safety program important in relation to the other programs being put forward by the President's budget?

Response. FDA's total request for 1991 for its Foods program is $202.6 million, including 2,717 FTEs. Included in this total is over $25 million in selected program increases. There is a $3 million increase for forensic chemistry research, and other increases of $2 million for research and consumer aassurance efforts in such areas as salmonella in eggs and the use of L-tryptophan supplements. In addition, there are increases of $6.6 million for increased inspections of food plants and surveillance of imported foods, and increases of $14 million related to enhanced research and surveillance over seafood.

FDA's food safety program is important because FDA is responsible for assuring that the food available to the nation's consumers, except for meat and poultry which are inspected by USDA, is safe, sanitary, and wholesome. Food safety issues which confront FDA today are significantly more numerous and vastly more complex than those which needed to be addressed when the first Federal food and comestic legislation was passed over 80 years ago. Today, for instance, the output of the domestic food industry approaches 300 billion pounds annually, and another 31 billion pounds of food products are imported from other countries each year.

As the size and output of the regulated food industry has grown, there has been a significant increase in the type and complexity of health concerns related to foods. Emerging microbial pathogens, such as *Listeria* and *Shigella*, are increasingly found in a variety of foods and are implicated as causes of illness outbreaks and sometimes death. Particular species of other pathogens which were once thought to be relatively harmless, for example *Salmonella enteritidis*, are now a major cause of foodborne illness outbreaks. More foods available to consumers are the convenience varieties, which require little or no preparation before eating. Because these products are not heated at temperatures sufficient to kill bacteria before consumption, any post-processing contamination with pathogenic microorganisms could cause them to be serious potential health hazards. Moreover, new safety questions are raised by the increasing use of technological innovations in food containers and storage, such as flexible pouches and shelf stable products; in food processing with the use of computer controlled systems; and in food production employing aspects of biotechnology.

In addition, there are a number of other important food related health concerns to which the Agency now must respond. Included among these concerns are the links between diet and degenerative disease, the potential chronic effects of illnesses induced by bacterial toxins, the impact of bacterial toxins and other food components on the human immune system, and the safety and efficacy of diet therapies for medical conditions.

We understand that the request for several agencies of USDA includes initiatives to develop much broader data on the use of pesticides on the farm , as well as more testing in food products, in conjunction with the States. FDA believes that better data on the use of pesticides, in particular, would be useful and would help us in planning our testing programs.

However, we are not familiar with the full details of the USDA initiative, and would defer to them on this issue. FDA spends over $25 million a year in its pesticide activities, and I believe we have a very effective program to screen for violative products. We also endeavor to inform the public that, because of FDA monitoring and screening activities, pesticide residues at levels currently found do not pose a general threat to health.

STAFFING NEEDS

Mrs. SMITH. In reviewing your statement, Commissioner Benson, you cite that the FDA is presently conducting approximately 18,000 inspections—roughly 32 percent fewer inspections than just five years ago. Many of these scheduled inspections are of drug and device firms, food establishments, and other laboratories.

To respond to this situation, the FDA has requested a $11.9 million increase in its budget. Would you briefly explain to the committee the importance of these inspections and the reason this increase is so badly needed by the FDA?

RESPONSE. The inspection of food, drug, device and other establishments that FDA regulates is very important because the vast majority of the information about an establishment's ability to manufacture or process products that will not be harmful or defraud consumers is through on-site inspection. Indeed, nearly all FDA compliance activities are in response to or are predicated upon data supplied through FDA field inspections and other FDA investigations. FDA inspections which are unannounced, have, in and of themselves, an important deterrent effect and thus support a vast array of industry decisions that foster consumer protection without direct FDA intervention. To the extent that FDA can increase the frequency of these inspections, the greater their deterrent effect. This increase of 125 FTE's for the field for this purpose makes an important step in restoring FDA's field strength.

Biennial inspections, once every two years, is required by law for drugs and devices. Unfortunately, we have not been able to meet this requirement the last few years due to the necessary diversion of resources to emergencies such as the Chilean fruit incident and major unplanned work such as generic drugs investigations. The situation is even more severe in the inspection of food establishments where the cycle of inspectional coverage is now about once every seven years.

ORPHAN REPORT

Mr. **CONTE**. The House report for fiscal year 1990 contained a provision I inserted calling for you to review and respond to the recommendations of the National Commission on Rare Diseases by December of last year. It's March 14, 1990, and I have seen nothing from the FDA. Why not? Is this a sign of the low priority you have placed on orphan and rare diseases?

Mr. **BENSON**. I want to assure you that the agency considers its responsibilities toward the development and regulation of therapeutic and medical products directed toward orphan diseases to be of utmost importance. To this end, we were very thorough in our review of the recommendations of the National Commission, particularly as these recommendations impacted upon FDA's responsibilities. Our response has received all appropriate clearances, and the report should reach the Committees very soon.

ORPHAN GRANTS AND CONTRACTS

Mr. **CONTE**. You have included a $270,000 increase in the amount for orphan product development grants and contracts. What did you originally request from HHS and OMB for this account?

Mr. **BENSON**. FDA's FY 1990 appropriation included an increase of $2.5 million for orphan product grants and contracts for a total of $7.5 million. Our request to Congress for an increase of $270,000 in FY 1991 reflects our estimate of the inflationary cost of continuing this level of grant and contract activity in FY 1991. Our previous requests to HHS and OMB did not reflect the final 1990 appropriation, and included an allowance for inflation over the 1989 level of $5.4 million.

ORPHAN PRODUCTS FOR AIDS DATABASE

Mr. **CONTE**. You note that you have begun to develop a database to identify orphan designation of products for the treatment of AIDS. What is the status of the database development effort, and how else will it be used beyond identifying AIDS treatments products?

Mr. **BENSON**. Within the Office of Orphan Products Development, FDA maintains a comprehensive database on all designated products for orphan diseases. From this database, other databases can be developed specifically geared to particular diseases. Our AIDS database contains those elements of data necessary to track designated orphan products for the treatment of AIDS. This is designed primarily to assist FDA staff in cross-referencing information between orphan products programs and AIDS programs.

Mr. **CONTE**. What is the cost of developing the database, and from what account does the funding come?

Mr. **BENSON**. Since our AIDS orphan products database is part of a comprehensive computer database network for designated orphan products, there is no significant separate cost in developing the AIDS database. The cost of the orphan products database is a relatively minor operating cost within FDA's Salaries and Expenses appropriations.

JAMES O. MASON

Assistant Secretary for Health
Department of Health and Human Services

James O. Mason, M.D., Dr. P.H., was sworn in April 21, 1989, as Assistant Secretary for Health, Department of Health and Human Services. Dr. Mason was nominated by President Bush April 7, 1989, and confirmed by the Senate April 19, 1989.

Before assuming responsibility for the U.S. Public Health Service, Dr. Mason had served, since 1983, as director of the Centers for Disease Control and administrator of the Agency for Toxic Substances and Disease Registry. During his tenure at CDC, Dr. Mason also served as acting Assistant Secretary for Health from February to December 1985. Dr. Mason served as executive director of the Utah Department of Health, with responsibility for health and health care financing, from 1979 to 1983. He was associate professor and chairman of the Division of Community Medicine, Department of Family and Community Medicine, at the University of Utah College of Medicine from 1978 to 1979. He directed a multiple-hospital health care corporation owned by The Church of Jesus Christ of Latterday Saints from 1970 to 1975.

As Assistant Secretary for Health, Dr. Mason directs the activities of the Public Health Service, which includes eight agencies: the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; the Indian Health Service; and the Agency for Health Care Policy and Research.

Dr. Mason provides policy guidance as well for HHS programs outside of PHS, and maintains relationships with other government and private agencies concerned with health. He advises and assists the Secretary on health policy and on all health-related activities of the department.

Dr. Mason was born June 19, 1930, in Salt Lake City, Utah. He received his B.A. and M.D. degrees from the University of Utah in 1954 and 1958. He received his master of public health and doctorate of public health from the Harvard School of Public Health in 1963 and 1967. Dr. Mason served his internship at Johns Hopkins Hospital in Baltimore from 1958 to 1959, and was an internal medicine resident at Peter Bent Brigham Hospital, Harvard Medical Service, in Boston from 1961 to 1962.

He has received numerous honors and awards. Among these are the Public Health Service Distinguished Service Medal (1988) and the University of Utah's Distinguished Alumni Award (1973). He is a member of a number of honorary and professional societies including the American Medical Association, the Institute of Medicine of the National Academy of Sciences, and the American Public Health Association. He has served on many national and international committees, councils, boards and task forces, including the United Nations Development Program/World Bank/World Health Organization Special Program for Research and Training in Tropical Diseases, Scientific and Technical Advisory Committee; and the National Institutes of Health Recombinant DNA Advisory Committee.

Dr. Mason is certified by the American Board of Preventive Medicine. He has written numerous articles and book chapters on a wide range of subjects related to the prevention and control of disease. He is a national spokesperson on the prevention and control of infectious disease, chronic disease and injury, and a leading architect of public policies concerning these health problems.

Dr. Mason and his wife, the former Marie Smith, have five sons and two daughters: James, Susan, Bruce, Ralph, Samuel, Sara and Benjamin.

OPENING REMARKS BY DR. MASON

Mr. Chairman, I am glad to have this opportunity to appear before you in support of FDA's budget request.

The Public Health Service, as you know, is committed to the achievement of better health for our nation's people through such efforts as disease prevention, health promotion, and the maintenance of a strong research capability. FDA's regulatory activities are a unique and essential part of this overall effort of the Public Health Service, its particular mission directed toward the promotion and protection of the health of the American public. FDA carries out its responsibilities through a wide range of activities: product review, postmarketing surveillance, inspections, regulatory action, rulemaking, standard-setting and public education.

As you are aware, FDA's efforts this past year were affected by the revelations concerning unethical conduct on the part of a small number of FDA employees and by several generic drug firms. I would like to assure the Committee that FDA has been moving forward in implementing a comprehensive corrective action plan which was announced by Secretary Sullivan last August, the key elements of which included intensified inspections, product sampling, and a reorganized and strengthened generic drug review process. Fortunately, FDA's continuing investigations - and those of others - have not revealed any evidence to date that the public health has been jeopardized. I am confident that this will remain the case and that the

Agency will not rest until all public confidence in the safety and effectiveness of generic drugs is justifiably restored. To help achieve this objective we are requesting a fiscal year 1990 supplemental of $13.9 million to be financed through the collection of user fees from the generic drug industry.

As with all of the Public Health Service, FDA remains committed to the conquest of AIDS by providing the most timely, effective, and efficient research and premarketing review possible of products that offer promise for diagnosing, treating, curing, or preventing AIDS or AIDS-related diseases, and by continuing to assure a safe supply of blood and blood products. To this end, FDA is requesting AIDS resources in their budget which I fully endorse. There is no consolidated PHS AIDS request this year as there was last year.

I am confident that FDA will continue to improve its ability to carry out its many responsibilities to protect the consumer and improve the public health. The budget request before you would provide for increases to enhance FDA's capability, and I fully support that request. This year, we are asking that industry support the cost of FDA's pre-market review activities. Since the sales of these products rely on FDA's ability to assure the public that they are safe, it is appropriate that the cost of determining that safety be born by industry.

Mr. Chairman, with your approval, I would be pleased to have Acting Commissioner James Benson proceed at this time with his opening statement.

James S. Benson
Acting Commissioner
Food and Drug Administration

Mr. James S. Benson, Acting Commissioner of the Food and Drug Administration, was born on March 23, 1939, in Baltimore, Maryland. He received a B.S. degree in civil engineering from the University of Maryland in 1962 and a M.S. degree in nuclear engineering from the Georgia Institute of Technology in 1967.

(Mr. Benson is FDA's Deputy Commissioner. Since December 1989 he has been serving as the Acting Commissioner pending the President's nomination of a new commissioner.)

As a member of the United States Public Health Service (USPHS), Mr. Benson served as the State Assignee to the Wyoming Health Department from 1962 to 1964, and as the State Assignee to the Georgia Health Department, from 1963 to 1965, working in the area of radium management. In 1965, he became a member of the Division of Radiological Health in the USPHS Radioactive Materials Section, remaining through 1966. From 1967 to 1970, Mr. Benson worked with the Bell and Howell Human Development Institute, initially as Management and Training Consultant, and later as Director of Operations. He joined the Westinghouse Learning Corporation as Director for Manpower Programs in 1970, leaving in 1971 to return to government service.

At that time, Mr. Benson rejoined the FDA Bureau of Radiological Health, and in 1972 was appointed Director, Division of Training and Medical applications. He was appointed Deputy Director, Bureau of Radiological Health, in 1976 and served in that position until 1982 when he became Deputy Director, Center for Devices and Radiological Health with the 1982 combination of the Bureaus of Radiological Health and Medical Devices. He assumed his current position as Deputy Commissioner in 1988.

During his years of government service Mr. Benson has received numerous awards. In 1978, he received the FDA Award of Merit, and the PHS Superior Service Award in 1984. In 1985 he was awarded the FDA Commissioner's Special Citation and the Meritorious Presidential Rank Award. In 1988, he received the Distinguished Presidential Rank Award; in 1989, he was selected as one of ten executives and organizations for the 1989 Profiles in Excellence by the Office of Personnel Management.

Mr. Benson and his wife Karen have two children and reside in Rockville, Maryland.

JOSEPH A. LEVITT, ESQ. is the Director of Executive Operations for the Food and Drug Administration and serves as Chief of Staff to the Commissioner. He joined the Commissioner's Office in May 1983 when he became the Commissioner's Program Advisor. He then became the Executive Assistant to the Commissioner in December, 1984, and assumed his current position in February 1988. Prior to joining the Commissioner's office, he worked in FDA's General Counsel's office since graduating law school in 1978.

Mr. Levitt is directly involved in a wide range of public health and administrative issues, including a central involvement in the development of the new regulations for drugs to treat life-threatening illnesses and the Treatment IND regulations. Mr. Levitt has also been heavily involved in such issues as AIDS, food labeling, generic drugs, and food safety. Other issues of past involvement include Reye syndrome, aspartame, sulfites, the IND/NDA rewrites, direct-to-consumer advertising of prescription drugs, medical devices, and the FDA Action Plan.

In 1982, 1985 and 1987, Mr. Levitt received the FDA Award of Merit, and the Commissioner's Special Citation in 1985. Mr. Levitt also received the PHS Superior Service Award in 1986, the Department Distinguished Service Award in 1988, and the Secretary's Special Citation in 1989. He graduated cum laude with a J.D. from Boston University, where he was a member of the law review. Mr. Levitt's B.A. degree is from Cornell University, where he graduated magna cum laude. Mr. Levitt is a member of the Massachusetts Bar and the Phi Beta Kappa Society.

RESUME

Margaret Jane Porter

Professional Experience

Oct. 1989- Present	Chief Counsel, Food and Drug Division, Office of the General Counsel, United States Department of Health and Human Services
1986-89	Deputy Chief Counsel for Social Security Programs Social Security Division, Office of the General Counsel, United States Department of Health and Human Services
1983-86	Supplemental Security Income Branch Chief, Social Security Division, Office of the General Counsel, United States Department of Health and Human Services
1977-83	Staff Attorney, Health Care Financing and Human Development Services Division, Office of the General Counsel, United States Department of Health and Human Services
1971-74	Administrative and Editorial Assistant Government Documents Cataloger Special Recruit Library of Congress

Education

Harvard Law School Cambridge, Mass.	J.D. cum laude	1977
University of Illinois Urbana, Illinois	Masters in Russian History Masters in Library Science	1973 1970
Colorado State University Ft. Collins, Colorado	B.A., Modern Languages	1969

Bar Admission

District of Columbia Court of Appeals
Supreme Court of the United States

Honors and Memberships

Office of the General Counsel Exceptional Service Award, 1988
Health Care Financing Administrator's Citation, 1981
Federal Bar Association

Margaret Jane Porter has been Chief Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services since October 1989. Ms. Porter began her legal career in the Department in 1977, first serving as a staff attorney in the Health Care Financing and Human Development Division for six years, working on Medicare and Medicaid matters, then serving as Social Security Income Program Branch Chief from 1983-1986, then Deputy Chief Counsel for Social Security Programs from 1986-1989. Ms. Porter holds a law degree from Harvard.

SHARON SMITH HOLSTON

ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS

Serves as principal advisor to the Commissioner for all phases of management inherent in the operations of FDA. Responsible for the effective utilization of all management resources and the implementation of operating programs by coordinating the funding, personnel, facilities, procurement, grant and contract management data processing, and safety and security needs of the Agency.

Received B.A. degree in French language and literature from Barnard College, Columbia University in 1967. Received M.P.A. degree from the John F. Kennedy School of Government, Harvard University in 1986.

Joined the federal government in 1967 as a Personnel Management Specialist for the U.S. Commission on Civil Rights. Served on the Welfare Reform Planning Staff in the Department of Health, Education, and Welfare from 1970 to 1972. Came to FDA in 1972 as Deputy EEO Officer for the Office of the Commissioner. Worked in the Division of Personnel Management from 1975 to 1977. Served as Acting Executive Officer for the Office of the Commissioner from 1977 to 1979 and Special Assistant to the Associate Commissioner for Management and Operations from 1979 to 1980. Served as Deputy Associate Commissioner for Management and Operations from 1981 to 1986 and Acting Associate Commissioner for Management and Operations from 1986 to 1988. Appointed to current position in 1988.

Received an FDA Award of Merit in 1982 and 1987, the Commissioner's Special Citation in 1985, and the DHHS Senior Management Citation in 1988.

FRANK P. CLAUNTS

POSITION: Director, Division of Financial Management
Office of the Associate Commissioner for Management and Operations

BIRTHPLACE AND DATE: Bartlesville, Oklahoma, September 5, 1942

EDUCATION: Bachelor of Arts, Texas Tech, June 1964
Master of Business Administration, American University, May 1975

HONORS AND AWARDS: Food and Drug Administration Commissioner's Special Citation, 1989; Public Health Service Superior Service Award, 1988; Food and Drug Administration Award of Merit, 1987; Food and Drug Administration Commendable Service Award, 1980.

EXPERIENCE: July 1980 to Present, Director, Division of Financial Management, Food and Drug Administration; September 1977-June 1980, Director, Division of Management Services, Food and Drug Administration; July-September, 1977, Special Assistant to the Associate Commissioner for Management and Operations, Food and Drug Administration; August 1976-June 1977, Legislative Analyst, Office of Management and Budget; July 1972-August 1976, Management Analyst, Food and Drug Administration; June 1971-May 1972, State Director of the Peace Corps in Bihar, India; July 1969-June 1971, India Desk Officer, Peace Corps, Washington, D.C.; September 1966-July 1969, Peace Corps Field Officer in north-eastern India; June 1964-June 1966, Peace Corps Volunteer, Tripura, India.

STATEMENT

BY

JAMES S. BENSON

ACTING COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON RURAL DEVELOPMENT, AGRICULTURE

AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

UNITED STATES HOUSE OF REPRESENTATIVES — MARCH 15, 1990

Mr. Chairman, I thank you for the opportunity to appear before your subcommittee today to support the Food and Drug Administration's budget request for 1991. I would first like to introduce my colleagues at the table with me...other members of my staff are also present to respond, if necessary, to specific questions and interests of the Committee.

I would like to review our activities this past year in relation to the selected increases we are proposing in our 1991 request.

First and foremost, FDA's performance of its regulatory responsibilities was severely challenged this past year by the difficulties associated with generic drugs. The agency is pursuing a plan to correct the problems found and we are confident that with your continued support, we will be successful. I will be bringing you up to date on this situation a little further on in this statement.

My remarks will contain a brief discussion of our need to restore our capacity in the field to deal with inspection and enforcement. I would also like to briefly summarize FDA's activities with regard to AIDS and AIDS-related diseases. In addition, I want to discuss the improvement of our evaluation of drugs, biological products, and medical devices for safety and effectiveness, our orphan product activities, and our efforts to combat the problems associated with food safety, especially seafood. Finally, I would like to report on our progress with regard to FDA's facilities needs.

Generic Drugs

The generic drug industry, and FDA's regulation of that industry, came under intense public scrutiny this past year as a result of revelations concerning improprieties on the part of several FDA employees, as well as fraudulent conduct by certain drug firms who falsified or misrepresented information in their applications. These incidents led to the development of a comprehensive plan of action which incorporated two goals: enhancement of the agency's capacity to ensure that the American public has access to quality generic drugs, and fortification of the generic drug approval process in order to maximize system integrity and fairness, providing adequate safeguards against fraud. This plan was announced by Secretary Sullivan last August, and our budget request includes resources to implement it both this year and in 1991.

The plan includes increased, continuing surveillance of the generic drug industry, including both plant inspections and product testing, combined with investigations to assure information provided to us is valid. Also included are enhanced application review activities as well as the establishment of an ombudsman function to provide for resolution of disputes with firms--not just generics but all the industries we regulate. The cost of the additional resources necessary to support this plan in 1990 was estimated at $17.9 million and 185 FTEs, of which $4 million was included in FDA's 1990 appropriations. We are requesting supplemental spending authority for the balance, $13.9 million, to be offset by fees to be paid by the industry. Appropriation language is being proposed which will permit the Secretary to establish and implement fees for applications to market generic drugs and annual fees to holders of approved applications to support increased inspections and product monitoring. We believe that the industry will benefit from the restored public confidence that sustained and enhanced FDA efforts will assure.

Although investigations to date have revealed the involvement of only a small number of firms in intentional deceit, and FDA's testing has not revealed widespread safety concerns, the problems discovered demand that we sustain an increased level of surveillance over all parts of the process. FDA is requesting a further increase of $10.2 million in 1991, primarily for improved application review activities and for applied research into complex bioequivalence issues, which will be offset by increased user fees.

Restoring FDA's Field Capabilities

Reduced levels of personnel over the last decade, coupled with the demands of the AIDS epidemic, the need to increase import activities, and emergencies such as the Chilean fruit tampering incident and urgent generic drug investigations, have had a serious impact on our ongoing monitoring activities. It became necessary to delay many scheduled inspections of drug and device firms, reduce the number of food establishment inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products. In 1989, we conducted approximately 18,000 inspections in this country, a decrease of [illegible] from five years earlier.

Even if the current rate of emergency problems were to decline in the near future, we would still need to provide for restoration of our field resources just to sustain reasonable levels of surveillance over the many products that we regulate, and to deal with problems which may be less immediate than the crises that have occurred over the past year. We are requesting an increase of $11.9 million and 125 FTEs to support this restoration of essential field capabilities, and thus work to prevent future product emergencies. I should add that included in this increase is $2.5 million to replace obsolete laboratory equipment to enable us to take more rapid advantage of new technologies as they come on the market.

AIDS

FDA continues to be very concerned about the individuals who are suffering from the devastating effects of AIDS and HIV diseases. We remain steadfast in our resolve to do all that we can to find a way to alleviate their suffering and provide hope for the thousands infected with this deadly virus. FDA's contribution in the fight against AIDS involves primarily our responsibilities for the premarket review of new drugs and biologics, including vaccines. FDA also plays a major role because of our responsibility for approving diagnostic and other testing products, and our duty to ensure the safety of the nation's blood supply. In addition, we are concerned with the safety and effectiveness of AIDS-related medical devices such as medical gloves and condoms. To ensure that newly developed products, reach AIDS patients as quickly as possible, new procedures were instituted at

FDA for reviewing these applications, and we have formalized procedures for making investigational drugs more widely available to those who are desperately ill. In July 1989, an expanded computerized listing of information on AIDS-related clinical trials became available to the public via a toll free telephone number. In September, 1989, this information was also made available to the National Library of Medicine subscribers through the AIDSTRIALS data base. This AIDS Clinical Trial Information Service, a cooperative effort of the FDA, the Centers for Disease Control, the National Institute of Allergy and Infectious Diseases, and the National Library of Medicine, provides the public with important basic information and guidance on clinical trials.

Coordinated expansion of efforts by industry, academia, and government to develop diagnostics, treatments, and vaccines for AIDS and HIV related illnesses continues to result in a growing number of product applications submitted to FDA for evaluation and licensing. As of November 1, 1989, the total number of AIDS-related investigational new drug applications (INDs) received for the treatment, diagnosis, and prevention of AIDS and AIDS-related diseases has risen to 295 from 59 in 1985, an increase of 400 percent. Zidovudine (commonly known as AZT), the only drug approved to treat HIV directly, has been approved in syrup form for treatment as well. Six other drugs have been approved for the treatment of AIDS-related conditions. These include both the injectable and aerosolized forms of the drug pentamidine to treat pneumocystis carinii pneumonia (PCP), an often fatal opportunistic infection associated with AIDS; two alpha-interferons to treat Kaposi's sarcoma, a cancer resulting from AIDS infection; ganciclovir to treat AIDS patients with sight-threatening cytomegalovirus (CMV) retinitis; and fluconazole to treat two serious AIDS-related fungal infections.

While a product is still being studied for safety and effectiveness, we have established procedures whereby, in some cases, the product can be made more widely available under what is called a "Treatment IND." Treatment IND protocols have been approved allowing for expanded distribution of the experimental therapies Dideoxyinosine (ddI) for the treatment of AIDS directly and r-erythropoietin for the treatment of anemia which often results from AIDS and from the administration of AZT. Most recently, a treatment IND has been approved to allow expanded distribution of the drug zidovudine for pediatric patients with advanced stages of infection with the AIDS virus.

In addition to our increasing attention to devices such as medical gloves and condoms that can help prevent the transmission of AIDS, FDA also continues to focus on activities aimed at educating the public and health professionals about the proper use and reuse of medical devices in order to prevent the inadvertant transmission of HIV. We produced this year, for example, a three-part videotape on appropriate infection control in dentistry.

Although the risk of acquiring AIDS by transfusion of blood has almost been eliminated, FDA continues its efforts to ensure the safety of the nation's blood supply. A 100 percent inspection of over 2400 FDA-regulated facilities was conducted once again last year. Our inspection program will continue to focus on procedures used by the blood and plasma industry in donor screening, testing for hepatitis B and HIV antibodies, and on procedures for quarantine and destruction of unsuitable blood products. For FDA's AIDS activities in FY 1991, we are requesting an increase of $ 6.6 million and 74 FTEs. This will support our ongoing commitment to expedite the review and evaluation of applications for all promising AIDS-related products, and to enhance our HIV-related applied research and product surveillance activities.

New Drug Review

Training, increased staff, and implementation of more efficient procedures have enabled the FDA to review a wide spectrum of new drugs and new medical devices more quickly in 1989, yet maintain the high standards of quality and safety expected of the agency. In calendar year 1989, we approved six new chemical entities in fourteen months or less, while approving a total of 85 new drug applications (NDAs). In addition, the number of overdue NDAs pending at the end of the calendar year was 67, reduced from 71 a year earlier, 91 two years ago, and 116 three years ago. I am not saying all problems in our review processes have been eliminated — only that we are working hard to maintain steady progress in improving these processes.

We continue to face an exploding universe of drug applications that involve more complex effectiveness and benefit/risk ratio decisions because of the new and highly complicated biomedical technologies being developed every day. We are requesting an increase of $2.5 million and 33 FTEs for new drug review in 1991 to help us sustain improvements achieved thus far and to meet the growing demands of increasing drug development.

Medical Devices and Radiological Health

FDA continues to make significant improvements to our medical devices and radiological health programs. FDA approved 56 premarket approval applications (PMAs) during 1989, the second-highest level ever. A record number of 510(k) premarket notifications - 7,022 - were submitted during 1989, an increase of 27 percent over 1988. Despite the increased workload, there were no active and overdue 510(k)s at the end of 1989. For the first time ever, FDA reached decisions on every investigational device exemption (IDE) within the 30-day statutory timeframe. Our medical device enforcement activities are increasingly effective in protecting public health. We issued 44 regulatory letters, and made 28 seizures. In addition 999 recalls were conducted, another all-time high. When combined with our efforts to educate and assist consumers, health professionals, and small manufacturers, we believe these, and other, FDA programs are contributing to significant improvements to product safety and effectiveness. We are requesting an increase of $2.3 million and 30 FTEs to help us sustain our level of review efforts in the face of increasing new device developments.

Orphan Products

The promotion and encouragement of the development of drugs, biologicals, medical devices, and medical foods for rare diseases or conditions continues to be one of our priority objectives. During calendar year 1989, 76 products received designation as orphan drugs. Since the enactment of the Orphan Drug Product Act, a total of 333 designations have been made. We estimate that another 135 sponsor requests for orphan drug designation will be received for review in 1991. In 1989, nine orphan drugs were approved for marketing. The $5.4 million available for orphan product grants in 1989 permitted the funding of 21 new grants in addition to continuing prior year grants. The increased 1990 funding of $7.5 million for these grants should provide for a significant increase in the number of new grants funded.

Seafood Monitoring

Seafood has become an increasing part of the American diet. Much of the seafood consumed in the U.S. is imported. FDA has been able to examine less than 6 percent of all formal entries of seafood imported into this country, and since seafood is susceptible to bacterial contamination, decomposition, and naturally occurring toxins, we have to be very cognizant about the quality of imported seafood. This becomes particularly vital because several types of the seafood can be consumed without cooking. At the same time, FDA needs to monitor the domestic processing industry, especially in the area of shellfish, since raw shellfish cause many of the illnesses related to seafood. In the shellfish program, we need to enhance our assistance to States, which bear responsibility for monitoring shellfish harvesting areas.

We are requesting an increase of $9 million to expand FDA's seafood activities in 1991 which includes more inspections, increased sampling of seafood products, particularly imports, and enhanced applied research to improve analysis of health risks and develop better detection methods.

FDA is also joining forces with the National Marine Fisheries Service of the Department of Commerce and the industry in a new initiative to develop an enhanced voluntary inspection and certification program that involves primarily in-plant inspections by NOAA Fisheries and verification of successful plant operations by FDA. This program, based on the existing authority within the Federal Food, Drug, and Cosmetic Act, will embody the "HACCP" (Hazard Analysis Critical Control Points) concept to assure seafood safety. Our budget projects that $5 million of the fees collected from industry will go to support FDA's portion of this program.

Food Safety Initiatives

In addition to the issues surrounding seafood, there are other issues regarding the safety of the nation's food supply at the forefront of our concerns for which we are requesting increases in our 1991 budget request.

During the 1980's we had to deal with a variety of real or threatened tampering incidents involving a wide range of FDA-regulated products. Until recently these episodes were confined to this country. The Chilean fruit incident of last year demonstrated that tampering can be an international problem. With the continuing growth of imported foods, the vulnerability of the food supply to such threats could also increase. We believe that we need a stronger base of knowledge on how specific poisons react over time in a large variety of potentially contaminated products. For this purpose, we are asking for an increase of $3 million in 1991 to enable us to conduct forensic research on the chemistry of possible poisons in a variety of products, develop testing methods so that we can respond more rapidly when incidents do occur, and provide expertise in a more proactive manner when the situation warrants.

We also need to sustain and enhance the base of applied research that provides the knowledge and tools to evaluate possible risks and develop the means to deal with them. An example of this need can be found in the persistent problem of salmonella in eggs. This is a particular challenge since the problem is not merely transmission of the bacteria through contact, but requires intensive investigation to determine how the bacteria is carried and transferred by chickens, their feed, or other products. New laboratory methods for prompt and accurate testing are needed to reduce the problem. Another example is presented by the recently-discovered relationship of a rare disease to certain products containing L-tryptophan. In this instance, we need to improve our applied research in order to be better able to analyze these products as well as to evaluate the precise source of the risk. We are asking for an increase of $2.0 million in 1991 to support these enhancements of our applied research program concerned with such food safety issues.

Facilities

Although we have faced a series of delays in completing and occupying the building we have referred to as "module 1" at Beltsville, MD., we now expect to occupy this new laboratory before the end of 1990. While this building will house only about 260 employees, it will provide modern state-of-the-art laboratories for them, replacing a small portion of the badly out-of-date laboratories we occupy at Federal Building 8 near here. Also, we have now resolved with NIH the precise location of our new AIDS building that will be located with our other facilities at the NIH campus, and the detailed planning for that building is finally proceeding.

In the long run, however, FDA still needs a new comprehensive plan for the Agency's headquarters facilities. We are working very closely with GSA staff in analyzing the requirements for FDA operations in the Washington area, and over the next year they will be helping us develop a facilities detailed programming document so that funding options and various modes of acquisition can be considered. We believe this detailed analysis of our needs will serve as an important basis for making decisions on consolidating FDA's Washington area facilities.

At the same time, we must maintain our existing facilities--our ability to conduct sound regulatory research and testing depends upon adequately functioning facilities and equipment. Our request for 1991 includes $4.7 million for facility maintenance and laboratory renovation projects, most of which is for NCTR and our field laboratories, which will not be affected by possible future headquarters facility consolidation.

SUMMARY OF BUDGET REQUEST

In conclusion, I would like to summarize several points about our 1991 budget request.

Our total request for 1991 is for $685.2 million, of which $152 million would be derived from proposed product review and monitoring charges. Another $5 million is expected to come from voluntary fees for seafood inspection. The request includes a net change of $31 million to provide for increased payroll and other operating costs. In addition, our request includes $53 million in program increases that I have already described in this statement. To summarize, increases of $10.2 million for generic human drug activities, $14.9 million for restoration of our field staff and enhancement of our forensic laboratory, $6.6 million for AIDS, $4.7 million for new drug and device review, $14.1 million for seafood monitoring, and $2 million for food safety initiatives are requested.

While we are certainly cognizant of the Committee's past guidance on the subject of user fees, we have once again included them in our request for certain of our activities because we believe them to be an equitable way to finance some FDA programs; this year, namely, review of applications for drugs, devices, antibiotics, biologics, and food additives ($124 million); enhanced generic drug review and monitoring ($28 million); and voluntary seafood certification ($5 million). With the exception of the seafood certification program, for which user fees are already authorized, the Administration is submitting a separate comprehensive legislative proposal to provide authority to charge these fees, for FDA. Our activities in these areas clearly benefit industry at the same time that they protect consumers, and so we believe these charges are appropriate.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions you or the other members of the Committee might have.

FISCAL YEAR 1991

Volume XII

Justification of Appropriation Estimates for Committee on Appropriations

Food and Drug Administration

FOOD AND DRUG ADMINISTRATION

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FOOD AND DRUG ADMINISTRATION
APPROPRIATION SUMMARY BY PROGRAM
($000)

Project	1989 Actual		1990 Estimate		Change in 1991		1991 Estimate	
	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years
Foods	$141,211	2,377	$164,178	2,412	$+38,391	+305	$202,569	2,717
Human Drugs	$131,215	1,913	$158,349	2,193	$+28,409	+163	$186,758	2,356
Biologics	60,471	674	65,372	745	+5,781	+38	71,153	783
Animal Drugs & Feeds	24,452	414	27,056	455	+3,624	+12	30,680	467
Total, Drugs	$216,138	3,001	$250,777	3,393	$+37,814	+213	$288,591	3,606
Devices & Rad. Products	$78,457	1,263	$87,160	1,300	$+10,622	+49	$97,782	1,349
NCTR	25,545	239	26,792	239	+1,093	---	27,885	239
Program Management	31,430	348	36,197	348	+1,784	---	37,981	348
Contingency Fund	---	---	1,975	---	-1,975	---	---	---
Total, Salaries and Expenses	$492,781	7,228	$567,079	7,692	$+87,729	+567	$654,808	8,259
Rental Payments	25,612	---	25,612	---	---	---	25,612	---
Buildings & Facilities	23,950	---	8,350	---	-3,598	---	4,752	---
Total Obligational Authority	1/ $542,343	7,228	2/ $601,041	7,692	$+84,131	+567	$685,172	8,259

Less: User Fees -157,175
(Proposed Legislation)
1991 Budget
Authority Request $527,997

1/ Includes $5,500,000 obligated from the Contingency Fund for AIDS-related work (as appropriated to this Fund during 1988. Excludes $63,000 unobligated balance lapsing.

2/ Includes supplemental request of $13,900,000, to be collected from user fees, for Generic Drug activities.

Summary of 1990 Current Estimate and 1991 Request

	FTE	$000
1990 Appropriation (Post-sequestration)	7,567	$587,141 1/
1990 Generic Drug Supplemental Requested (To be funded by user fees)	+125	+13,900
1990 Revised (Total 1990 FTEs including 185 in other accounts: 7,877)	7,692	$601,041
Less non-recurring costs:		
Contingency Fund		- 1,975
Change in Buildings and Facilities		- 3,598
Built-in Changes:		
Cost of 1/90 Pay Raise		+11,730
50 Percent of FY91 Pay Raise costs		+ 5,308
Personnel related costs		+ 5,984
Other operating costs		+13,688
1991 Current Services	7,692	$632,178
Program Increases:		
AIDS	+ 74	+ 6,644
Field restoration/forensic laboratory	+150	+14,850
New Drug Review	+ 33	+ 2,475
New Device Review	+ 30	+ 2,250
Generic Human Drugs	+ 69	+10,200
Seafood Monitoring	+180	+14,075
Food Safety Initiatives	+ 25	+ 2,000
National Vaccine Program	+ 6	+ 500
1991 Estimate/Spending Authority	8,259	$685,172
Less: User Fees Proposed		-157,175
1991 Estimate/ Budget Authority	8,259	$527,997 1/
FTEs in other accounts	+185	
	8,444	

1/ Both 1990 and 1991 estimates above include $25,612,000 for Rental Payments to GSA. The 1990 appropriation includes $8,350,000 and the 1991 estimate includes $4,752,000 for Buildings and Facilities. The above estimates also include $56,220,000 in 1990 and $63,236,000 in 1991 for AIDS related work.

FOOD AND DRUG ADMINISTRATION

Highlights of the 1991 Budget Justification

The 1991 budget request of $685.2 million for the Food and Drug Administration includes $528.0 million in budget authority plus $157.2 million from collections of proposed user charges. The request maintains the current level of program operations by providing for increased payroll and other operating costs (+$36.7 million), offset by non-recurring costs in the Contingency Fund and Buildings and Facilities (-$5.6 million), and allows for selected program increases (+$53.0 million). A legislative proposal will provide authority for product review charges to offset costs of reviewing manufacturers' applications for human and animal drugs, medical devices, food additives, and biological products, as well as charges to generic drug manufacturers for enhanced monitoring of those products. In addition, FDA plans to implement a program of voluntary inspection and certification of seafood processors under existing authority of the Food, Drug, and Cosmetic Act.

User Fees

The President's 1991 Budget proposes user fees for certain FDA activities, including FDA's review of applications for new products, post-market surveillance of generic drug products currently on the market, and enhanced inspection and certification of seafood.1/ FDA will devote more resources to the review of new products and thus bring more of these products to the marketplace more quickly.

The Administration continues to believe that user fees are an equitable way to finance some FDA programs. The principles underlying the position are:

FDA User Fees Are Fair:
Identifiable beneficiaries of government services should pay the full cost to the government of providing those services.

Industry Derives Private Benefits From FDA Services:
FDA review and inspection activities impart substantial private benefits to industry, including reduced liability due to federal safety regulations and technological assistance from FDA scientists who review applications. The $157 million in user fees will capture only a portion of these private benefits.

Industry Profits From Quicker FDA Approval:
The length of the FDA review and approval process has a direct impact on industry profits.

1/ The President's FY 1991 Budget proposes to expand voluntary inspection of seafood processors under existing statutory authority in the Federal Food, Drug, and Cosmetic Act.

Proposed distribution of the fees by major product category is as follows:

Drugs, Devices, Antibiotics, Biologics and Food Additives	$124 million
Enhanced Generic Drug Review and Monitoring	28 million
Voluntary Seafood Certification	5 million
Total Collections	$157 million

Under this proposal, the FDA would be able to waive the fee requirement for certain products; orphan drugs and drugs designed to treat addiction might be among those for which the FDA would not charge fees.

1990 Supplemental Requested For Generic Drug Activities

On August 18, 1989, Secretary Sullivan announced a plan to deal with the problems that had been discovered with generic drugs. This plan included increased, continuing surveillance of the generic drug industry, including both plant inspections and product testing, combined with investigations to assure the accuracy of data submitted to FDA with generic drug applications. This plan also included enhanced application review activities to assure the safety and efficacy of generic drugs, to provide thorough quality control of the process to prevent any improprieties, and to maintain prompt review by FDA; as well as the establishment of an ombudsman function to provide for resolution of disputes with firms.

As part of this plan, the Secretary announced plans to institute charges to the industry to pay for the cost of these changes within FDA. The cost of the additional resources needed for FDA in FY 1990 was estimated at $17.9 million. Final Congressional action on FDA's FY 1990 appropriations included an increase of $4 million for generic drug activities, which will support 60 of the 185 additional FTEs needed to restore and sustain public confidence in generic drugs. A Supplemental Appropriation of $13.9 million is necessary to support the additional 125 FTEs needed and provide the additional laboratory equipment and contracts necessary to sustain a sound base of product evaluation and Field surveillance over this industry.

This supplemental funding will be offset by fees to be paid by the industry. The appropriation language proposed will permit the Secretary to establish and implement fees for applications to market generic drugs and fees to holders of approved applications to support increased inspections and product monitoring. The industry will benefit from the restored public confidence in generic drugs that sustained and enhanced FDA efforts will assure. Also, the integrity and availability of generic drugs can result in savings throughout the health care delivery system, including third-party payers, especially Federal health care programs.

During FY 1989, FDA had to devote 146 Field FTEs alone to the emergency inspections and product testing of generic drugs. FDA cannot continue to divert this level of resources to this program without severe impacts on other FDA programs. As a result of generic drugs and other emergencies, FDA's inspections of regulated firms in this country continued to decline, to a level 32% lower than five years ago. It should be noted that although a portion of the retrospective review of the generic drug industry has been completed or is under way, FDA must continue to monitor the industry closely, and provide thorough scrutiny and investigations for new applications. FDA cannot be viewed as having done a one-time sampling of the industry and its products and then returned to business as it was before.

Although the problems discovered in this industry apply to a small number of firms, and FDA's testing has not revealed widespread safety concerns with generic drugs, the problems certainly demand a sustained increased level of surveillance over all parts of the process. For example, FDA had not previously conducted investigations to verify the validity of bioavailability studies submitted to the agency as part of generic drug applications, but this is an area where several important discrepancies have been found. The agency must establish and sustain new means to monitor this and other parts of the evaluation process.

1991 Increase for Generic Drugs

The 1991 request includes a further increase for the generic drug program. This increase is primarily for application review activities to assure thorough and prompt review of all new applications, and applied research to provide the scientific basis for expeditious resolution of complex bioequivalence issues. Field surveillance will continue at approximately the 1990 level, including thorough investigation and monitoring of new products, continued testing of products on the market, will utilize the resources required in 1989 and 1990 for investigations related to current products. The 1991 estimates include an increase of 69 FTEs and $10.2 million for this program.

AIDS

This request includes funding for FDA's work related to AIDS, within the applicable programs. FDA's 1990 Appropriations, after sequestration, include $56.2 million for these activities; the 1991 request includes an increase of $7 million to a total of $63.2 million for AIDS-related work. These increases are included in the Human Drugs, Biologics, and Medical Devices sections of this justification.

FDA's contribution to the fight against AIDS is vital not only because of the Agency's regulatory role but also because of its knowledge and experience in disease therapy by drugs, disease prevention by vaccines, and ensuring the safety of the blood supply. FDA must not only review product applications for potential drugs, vaccines, and screening tests to assure that the products are safe and effective, but FDA must also deal with related issues in the area of medical devices--for example, by assuring the effectiveness of barrier products like rubber gloves and condoms.

FDA has received over 300 Investigational New Drug (IND) applications representing over 190 different products for the prevention, diagnosis, or treatment of AIDS and related diseases. In many of these cases, FDA granted permission to begin clinical trials within five days of receiving an application. Applications continue to be received at an increasing rate.

FDA must be prepared to evaluate these complex applications as expeditiously as possible. In addition, FDA must monitor the progress of an increasing number of studies under way, and must continue to intensify its efforts to assure the safety of the blood supply, because of the increasing complexity of tests required to prevent transmission of the disease.

Expanded activities by industry, academia, and FDA to develop treatments for AIDS have significantly increased the number of product applications submitted for FDA evaluation. In addition to product application reviews, FDA must inspect manufacturing establishments, and develop standards and methodologies for validation and testing strategies.

FDA will continue to expedite the review and evaluation of investigational new drug applications (INDs) and new drug applications (NDAs) for all promising AIDS-related therapeutics and facilitate therapeutics development and availability. This commitment on the part of FDA includes increased communication with sponsors regarding preclinical studies and clinical trial design and conduct, active monitoring of the progress of clinical trials, and increased reliance on postmarketing surveillance. FDA will expand upon the current practice of early and continued consultation between FDA and product sponsors.

FDA's applied research activities have played a significant role in the development of vaccines, therapeutic agents, and test kits for possible use in AIDS and AIDS-related conditions by defining parameters that must be met regardless of product or sponsor. FDA continues to enlarge the scope of its AIDS-related activities as new data on the AIDS virus and disease accumulates and clinical trials of new therapies, vaccines, and diagnostic tests expand.

Restoring FDA's Field Capabilities/Forensic Chemistry Research

The diversion of resources to handle emergencies such as the Chilean fruit tampering incident, and urgent generic drug investigations, has diminished FDA's ability to conduct its normal product and plant monitoring programs. FDA has had to devote 400 to 500 staffyears a year in recent times to cope with unanticipated emergencies. FDA has found it necessary to delay scheduled inspections of drug and device firms and blood banks, reduce the number of food establishment inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products.

To prevent future product emergencies, and restore essential Field capabilities, this request includes $11.9 million to support 125 FTEs and to provide urgently needed laboratory equipment. An aging analysis has shown that 47 percent of the Field's laboratory equipment is at or beyond the point of proper replacement, which if done in one year would require over $14 million. This request includes $2.5 million to replace equipment that is most out of date, which will reduce problems due to obsolete equipment and enable the agency to take more rapid advantage of new technology as it comes on the market, greatly increasing the efficiency of our Field scientists. These resources are included in the Foods, Human Drugs, Biologics, and Medical Devices program estimates.

Forensic Chemistry Research

During the 1980's FDA has had to deal with a variety of real or threatened tampering incidents involving a wide range of FDA-regulated products. Until recently, however, these episodes were confined to this country and were mostly localized. The Chilean fruit incident has now shown that tampering can be an international problem. With the continuing growth of imported foods, the vulnerability of the food supply to such threats could also increase. FDA has had to take primarily a reactive approach in dealing with such incidents. To respond as rapidly as possible, FDA needs a stronger base of knowledge on how specific poisons react over time in a large variety of potentially contaminated products. The 1991 estimate includes an increase of $3 million and 25 FTEs to conduct research on the chemistry of possible poisons in a variety of products, develop testing methods so that FDA can respond more rapidly when incidents do occur, and to provide expertise not only to other FDA offices but also to other Federal, State and local agencies.

Seafood

Seafood is becoming an increasingly larger part of the American diet. In addition, close to 65 percent of all seafood consumed in this country is imported, and FDA has been able to sample less than three percent of all imported seafood entries. Bacterial contamination, decomposition, naturally occurring toxins, and heavy metals are some of the primary concerns affecting seafood, both shellfish and finfish. A number of bacterial and viral illnesses are borne by seafood, and these hazards are often not destroyed by cooking because the product is eaten raw, or a prepared product is improperly processed.

The 1991 request includes increases totaling $14.1 million including 180 staffyears, to provide for increased inspections, sampling of seafood products, especially imports, applied research to provide for improved analysis of health risks and better detection methods, and increased public information and State liaison activities to assure the safety of seafood. Five million dollars of this effort is projected to be paid for by the industry, under present statutory authority, under an enhanced voluntary certification program being developed in conjunction with NOAA.

New Drug Review

Training,increased staff, and implementation of more efficient procedures have enabled the FDA to review a wide spectrum of new drugs more quickly in 1989, yet maintain the high standards of safety and quality expected of the Agency. In calendar 1989, FDA approved six new chemical entities in fourteen months or less, while approving a total of 85 new drug applications (NDAS). In addition, the number of overdue NDAs pending at the end of the calendar year was 67, reduced from 71 a year earlier and 91 two years ago. FDA continues to face explosions in the development of new and highly complicated biomedical technologies with a resulting increase in drug applications that involve more complex effectiveness and benefit/risk ratio decisions. An increase of $2.5 million in 1991, including 33 FTEs, will enable FDA to sustain improvements achieved thus far in the drug review process and to meet the growing demands of increasing drug development.

New Device Review

FDA seeks to assure the safety and effectiveness of the medical devices it regulates while at the same time avoiding unnecessary delays in the introduction of beneficial innovations. Major improvements have been achieved in recent years in the review process. For example, average review time within FDA for Premarket Approval Applications (PMAs) was reduced to about 8 months in 1989. However, the workload continues to increase, partly due to the increased complexity of technologies that must be evaluated. The 1991 increase of $2.3 million includes 30 FTEs to continue efforts to improve and expedite the device review process.

Additional Food Safety Initiatives

Just as FDA needs to restore its Field inspectional and product testing capabilities to ensure effective surveillance over products on the market, the agency also needs to sustain and enhance the base of applied research that provides the knowledge and tools to evaluate possible risks and develop means to deal with them. For example, the persistent problem of salmonella in eggs has provided a particular challenge since the problem is not merely transmission of the bacteria through contact, but requires intensive investigation as to how the bacteria is carried and transferred by chickens, their feed, or other products, and demands new laboratory methods for prompt and accurate testing to reduce the problem. A different problem is presented by the recently-discovered relationship of a rare disease to certain products containing L-tryptophan. In this instance FDA needs applied research to be better able to analyze these products as well as to evaluate the precise source of the risk. To enhance FDA's applied research into such food safety issues, the 1991 request includes an increase of $2.0 million including 25 FTEs.

Orphan Products

FDA continues to encourage and support the development and introduction into the market of new orphan products--drugs, devices, or other products for treatment of rare conditions or products for which sponsors lack economic incentives for development and marketing. In 1989, five orphan drugs were approved for marketing. In 1989, $5.4 million was awarded in grants for research on orphan products--21 new grants and continuation funding of 40 prior grants. As provided in the 1990 appropriation, funding of these grants will be $7.5 million in 1990, which should allow for a significant increase in the number of grants funded. The 1991 estimate includes $7.8 million for these grants.

Drug Abuse

Although FDA is a small part of the national battle against drug abuse, the agency continues to play an important role in some aspects of the problem. FDA will continue to strive to increase its assistance to methadone treatment centers to assure that they meet regulatory requirements for control and use of this drug. FDA monitors methadone narcotic treatment centers to determine compliance with narcotic treatment standards related to DEA registration.

In addition to enforcement of these regulations, FDA plans to continue to emphasize a positive approach to the monitoring of these centers by, for example, assisting them in improved recordkeeping, as well as aiding in the resolution of compliance problems. FDA will also continue its efforts against the illegal use of steroids, in conjunction with other Federal agencies, which resulted in the investigation of 140 individuals for illegal steroid activities in 1989. These and other activities related to drug abuse are estimated at $7.2 million for 1990, and will be continued at the level of $7.4 million in 1991.

APPROPRIATION LANGUAGE

[Salaries and] Program Expenses

For necessary expenses of the Food and Drug Administration; for rental of special purpose space in the District of Columbia or elsewhere; and for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; [$560,271,000: Provided, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided, further, That of the sums provided herein, not to exceed $2,000,000 shall remain available until expended, and shall become available only to the extent necessary to meet unanticipated costs of emergency activities not provided for in budget estimates and after maximum absorption of such costs within the remainder of the account has been achieved] $527,997,000, of which $25,612,000 shall be /1 for payment of rent and related costs pursuant to section 210(j) of the Federal Property and Administrative Services Act; and of which $4,752,000 shall remain available until expended for construction, renovation of facilities, and facilities planning: Provided, That collections from user /2 fees specifically authorized by law may be credited to this account, to remain available until expended: Provided further, That funds provided under this heading may be used for one-year contracts which are to be performed in two fiscal years so long as the total amount for such contracts is obligated in the year for which the funds are appropriated: Provided further, That should the Food and Drug Administration require modification of space, the sums provided herein for rental and related costs may be increased or decreased by not more than 10 percent, and any such increase or decrease shall not alter the total amount available for this account: Provided further, That funds appropriated herein may be used to expand the level of rental space or services above those of fiscal year 1990. (Rural Development, Agriculture, and Related Agencies Appropriations Act, 1990.)

1/ The request for Program Expenses includes funding for Buildings and Facilities and Rental Payments to GSA, previously appropriated as separate accounts. The language proposed above would provide for limitations on these categories of expenses as well as possible adjustment of Rental Payments in the event space needs change, and extended availability of Buildings and Facilities funds, without the need for separate accounts.

2/ The proposed language pertaining to user fees will permit the crediting directly to this account of collections from new product evaluation fees and generic drug review and monitoring fees; new legislation will be proposed that will provide specific statutory authority for FDA to implement such fees.

1990 SUPPLEMENTAL APPROPRIATION LANGUAGE

Salaries and Expenses

(Appropriations Language now requested, existing legislation)

The Secretary of Health and Human Services is authorized to charge fees to applicants for and holders of approved applications, including pending applications, under section 505(j) of the Food, Drug, and Cosmetic Act, for fiscal year 1990, for federal costs associated with review of applications under such section. All such fees collected shall be credited to this account, and shall remain available for the costs of such activities, without fiscal year limitation and in the amounts provided in advance in appropriations acts. The Secretary shall determine the amounts of such fees and publish a schedule of fees which shall be effective upon publication, notwithstanding 5 U.S.C. 553.

For fiscal year 1990, from such fees collected, $13,900,000 shall be available for the cost of review of abbreviated applications pursuant to section 505(j), and for surveillance and testing of drugs marketed pursuant to approved applications under section 505(j).

SIGNIFICANT ITEMS IN APPROPRIATIONS COMMITTEE REPORTS

Fiscal 1990 House Report No. 101-137	Actions Taken Or To Be Taken
User Fees	
"... user fees require specific authorization which is not now available. In the future, the Committee expects the Department of Health and Human Services to submit its budget request based on current law."	The Administration believes, due to the necessity of reducing Federal deficits, that it is appropriate to charge industry for those costs of FDA's operations from which industry benefits significantly, including the approval of new products. Congress endorsed a government-wide collection target of $2.7 billion worth of user fees in the bipartisan budget agreement for FY 1990.
Food Safety	
"The Committee is concerned about the lack of uniformity in nutrition labeling. The Commissioner testified before the Committee that FDA has held consensus conferences with consumers, academia and industry groups with the goal of coming up with a uniform/mandatory nutrition label that would have consistency across the 50 States. Also as a result of a joint FDA/USDA task force, negotiations are in progress with the Institute of Medicine to expedite a project to enlist a panel of experts to revise and harmonize the nutrition related elements of food labeling. The Committee expects the Commissioner to continue these efforts and strongly encourages FDA to reach an agreement on a uniform nutrition label as quickly as possible."	FDA held a series of four public hearings in November and December of 1989 on food labeling to discuss issues related to nutrition labeling, among other things. These hearings were associated with an Advance Notice of Proposed Rulemaking (ANPR), published on August 8, 1989, that identified a series of issues in nutrition labeling for which the Agency requested comment. Approximately 1000 comments have been received on the food labeling issues identified in the ANPR. These comments are now under review and proposals are being prepared for changes in labeling. In an independent effort, the National Academy of Sciences, under joint funding by DHHS and USDA, is preparing a white paper on labeling changes.

Fiscal 1990 House Report No. 101-137	Actions Taken Or To Be Taken
Red Dye No. 3	
"The Committee expects the Food and Drug Administration to provide the technical expertise necessary for the development and design of protocols for a long-term study to determine if the secondary mechanism effect can be confirmed for FD&C Red No. 3. Such study shall be financed by the affected industries. The Committee further expects the Food and Drug Administration to review the results of this study, in addition to any other scientifically-based findings which may emerge, prior to making any decision relating to changes in the provisionally or permanently approved uses of this color."	As part of its responsibility for the review and approval of submitted food additive petitions the FDA does review the design of protocols for studies used to determine safety and offers advice to the petitioner. In the case of Red Dye No. 3, the Agency has provided advice on the design and adequacy of several pilot protocols that have so far been submitted. In each instance in the review of a food and color additive, including Red Dye No. 3, the Agency applies safety standards of the FD&C Act appropriate to the specific case. HHS Secretary Louis W. Sullivan, M.D., announced on January 19, 1990 that the FDA will terminate the "provisional" use of color additive FD&C Red No. 3. This action is required under federal law because laboratory tests have shown that very high doses of this red color additive administered in the diet of male rats were associated with thyroid tumors. After delisting the provisional uses, FDA will follow the mandate of the Delaney Clause and will take steps to eliminate the rest of the color's uses. These "permanently" listed uses of Red No. 3 for ingested drugs and foods may be legally continued until the process of de-listing them is completed. Again, this continued use is consistent with the very low public health risk involved.
Orphan Products Program	
"The Committee expects FDA to review and respond to the recommendations contained in the Report of the National Commission on Orphan Diseases and report to the appropriate Committees of Congress before December 1, 1989."	The complexity of the Commission's report required extensive review within FDA and thus delayed a response past the date requested. However, a report is now drafted and will be transmitted to the Committee in the near future.

Fiscal 1990 House Report No. 101-137	Actions Taken Or To Be Taken
AIDS Building	
"...The failure to expedite construction of this facility is unexcusable. The Committee does not want FDA to become the bottleneck to the development and introduction to the marketplace of any medical product. The Committee expects a quarterly report from the Secretary regarding the status of the new AIDS building."	An architectural firm has been hired and planning for this new building is underway. A report will be transmitted to the Committee in the near future.
Fiscal 1990 Senate Report No. 101-84	
User Fees	
"The Committee continues to expect FDA budget requests to be based on current law."	The Administration believes, due to the necessity of reducing Federal deficits, it is appropriate to charge industry for those costs of FDA's operations from which industry benefits significantly, including the approval of new products. Congress endorsed a government-wide collection target of $2.7 billion worth of user fees in the bipartisan budget agreement for FY 1990.
Agency Priorities	
"With the funds provided, the Committee expects FDA to assess the priority of its regulatory, research, inspection, and consumer education activities for each center; to calculate the number and skill levels of staff currently detailed to meet these activities; and to identify organizational, staff, and equipment changes necessary to meet evolving agency demands over time. In evaluating the agency's objectives, the Committee expects FDA to propose alternatives for low-priority activities and to improve product review and tracking systems.	The agency has initiated a comprehensive review of program priorities and resource needs. The agency will consult with GAO staff and provide information to the Committees on efforts to improve agency management as this review proceeds.

Fiscal 1990 Senate Report No. 101-84	Actions Taken Or To Be Taken
The Committee expects FDA to consult with the General Accounting Office (GAO) and to provide periodic briefings to the Appropriations Committees on the progress of its management control efforts."	
Recruitment of Medical Officers and Scientists	
"The Committee has not yet received the report requested by January 15, 1989, in the 1989 appropriations act on recruitment of medical professionals and other scientists at the FDA. The Committee directs the Commissioner of FDA to release this report directly to the Appropriations Committees by October 1, 1989."	The collection and analysis of much more data on agency recruitment than was available in the past has required a longer time than previously anticipated. However, this analysis is nearly complete and a report will be transmitted in the near future.
AIDS Building	
"The Committee concurs with the House in noting the lack of progress in construction and operation of the AIDS facility at the National Institutes of Health campus and expects to receive the progress reports as designated by the House."	Progress reports will be furnished to both House and Senate Committees.
Food Labeling	
"The Committee is disappointed with the slow pace and the mixed signals that the FDA has provided with respect to food labeling. The 1989 appropriations act instructed FDA to provide definitions for "commonly used, vague, and misleading nutritional and health labeling claims such as lite, low-fat, natural and others." While FDA is not the sole determining agency in the development of uniform nutrition labeling, it does play a leading role. Thus, the Committee directs FDA to move forward in making definitions available to the consumer to ensure that food safety is not compromised, especially in cases where dietary restrictions must be taken into account, such as in claims of fat versus cholesterol content."	As a follow-up to a proposed regulation on definitions for cholesterol content for the purpose of food labeling (Federal Register 51:42584-93, 1986), FDA is developing an additional proposal on definitions for fat content of foods. Upon receipt of comments on the proposal, a regulation on fat content descriptors will be prepared. In the Advance Notice of Proposed Rulemaking (ANPR), of August 8, 1989, comments were requested on the use in food labeling of such descriptors as "fresh", "lite", "natural" and others. FDA is reviewing the comments received and is in the process of preparing proposals on the use of descriptors and other food labeling issues.

Fiscal 1990 Senate Report No. 101-84	Actions Taken Or To Be Taken
Consolidated Facility	
"The Committee expects that FDA will work in conjunction with the General Services Administration [GSA] to proceed in planning a Maryland-based consolidated facility examining and taking into account alternatives that are most cost effective for the Federal Government over the long term, that include donated and federally owned property, and that include lease-purchase arrangements, but only where the lease installments are applied to the purchase price."	FDA is working closely with GSA on this planning. As directed by the Conference Report, a report will be furnished to the Committee in the near future.
Fiscal 1990 Conference Report (House Report No. 101-361)	
Management Improvement Systems	
"Within the increase provided, the conferees expect the Food and Drug Administration to implement management improvement systems and automated data processing enhancements necessary for centralizing its planning, ongoing oversight, and allocation of limited resources to priority activities among its various centers and field offices. Management information and automated processing systems development should include effective controls for review of foods, human and animal drugs, biologics, and medical devices; optical storage and retrieval technology;and computer-assisted review and tracking of product applications."	The agency is continuing and expanding its efforts to improve its information systems, especially in the areas of review of product applications and in coordinating information agency wide. Detailed information on recent accomplishments and plans are included in the ADP Summary section of this justification.
Training Programs	
"To enable FDA to recruit and retain qualified medical and scientific personnel imperative to meet statutory responsibilities, the conferees expect FDA to expand regulatory training and fellowship programs to create a larger pool of qualified candidates to fill agency staff requirements."	FDA is continuing to expand its training and fellowship programs. Detailed information on the status of these programs is included in the Program Management Status of Program section of this justification.

Fiscal 1990 Conference Report (House Report No. 101-361)	Actions Taken Or To Be Taken
Small Business	
"The conferees expect FDA to increase substantially its assistance to small businesses in order to meet FDA's complex regulatory requirements."	FDA has increased staffing in the Division of Small Manufacturers Assistance,and has continued efforts to provide improved guidelines for manufacturers in meeting regulatory requirements. Moreover, FDA is continuing efforts to provide guidance and encourage communication early in the product development process, so that product trials are designed to effectively determine the safety and efficacy of the product.
Generic Animal Drug and Patent Term Restoration Act	
"The conferees also expect FDA to implement the Generic Animal Drug and Patent Term Restoration Act within funds available."	Within the funds provided for 1990, FDA has allocated staffing increases to the Center for Veterinary Medicine,and some to other FDA components, to assure effective implementation of this Act.
Cosmetics	
"The conferees are also concerned with the results of the survey by FDA on microbial contamination in cosmetic makeup testers. The results of the survey indicated that at least five percent of the shared cosmetics studied were inadequately preserved, resulting in a level of microbial contamination that raises questions of consumer safety. As a result of these findings, the conferees expect FDA to develop microbiological testing procedures and regulations to ensure adequate preservation of shared and unshared products. FDA should cooperate with the cosmetic industry in the development of single cosmetic samples rather than shared samples. The conferees will expect FDA to submit a progress report by March 30, 1990."	The FDA currently has adequate methodology for the testing of samples of cosmetic products for microbial contamination. However, methodology for predicting adequacy of preservation requires somewhat different methodology and, more importantly, validated methodology, which is currently not available. FDA has been pursuing research aimed at the development of validated methodology to assess the adequacy of preservation of cosmetic products but a date of completion of this research cannot be predicted at this time. The development of regulations addressing cosmetic product preservation cannot be initiated until a suitable methodology is developed and validated. Further, the need for new regulations will depend on an

Fiscal 1990 Conference Report (House Report No. 101-361)	Actions Taken Or To Be Taken
	assessment of whether cosmetics that are adequately preserved present a safety risk when used under shared-use conditions. The development of regulations to address microbial hazards in both shared-sample and single user cosmetic products is subject to the full notice and comment rulemaking process which could require several years to complete.
	FDA continues to be willing to work with the cosmetic industry in areas of mutual interest relative to cosmetic safety issues. The Agency is aware that the cosmetic industry already possesses suitable technology for the development of single sample cosmetic testers and distribution for use at the retail level. The agency would be available to comment on data submitted by the industry in support of single sample cosmetic testers . The Agency will provide a status report by March 30, 1990.
Red Dye No. 3	
"The managers on the part of the House expect the Food and Drug Administration to provide the technical expertise necessary for the development and design of protocols for a long-term study to determine if the secondary mechanism effect can be confirmed for FD&C Red No. 3. Such study shall be financed by the affected industries. The managers on the part of the House further expect the FDA to review the results of this study, in addition to any other scientifically based findings which may emerge, prior to making any decision relating to changes in the provisionally or permanently approved uses of this color.	As part of its responsibility for the review and approval of submitted food additive petitions, the FDA does review the design of protocols for studies used to determine safety and offers advice to the petitioner. In the case of Red Dye No. 3, the Agency has provided advice on the design and adequacy of several pilot protocols that have been submitted. In each instance in the review of a food and color additive, including Red Dye No. 3, the Agency applies safety standards of the FD&C Act appropriate to the specific case. HHS Secretary Louis W. Sullivan, M.D., announced on January 19, 1990 that the FDA will terminate the "provisional"

Fiscal 1990 Conference Report (House Report No. 101-361)	Actions Taken Or To Be Taken
The managers on the part of the Senate believe that the FDA should reach its final decision on Red Dye No. 3 solely under the standards of the Food, Drug,and Cosmetic Act (21 U.S.C. 376 and the transitional provisions thereto, 74 Stat. 397, 203), and section 10(e) of the Administrative Procedure Act, 5 U.S.C. 706."	use of color additive FD&C Red No. 3. This action is required under federal law because laboratory tests have shown that very high doses of this red color additive administered in the diet of male rats were associated with thyroid tumors. After delisting the provisional uses, FDA will follow the mandate of the Delaney Clause and will take steps to eliminate the rest of the color's uses. These "permanently" listed uses of Red No. 3 for ingested drugs and foods may be legally continued until the process of de-listing them is completed. Again, this continued use is consistent with the very low public health risk involved.
Consolidated Facilities	
"The conferees will expect FDA to provide requirements development for necessary renovation and consolidation of FDA facilities. The conferees direct the FDA Commissioner to report concurrently to the appropriate committees of Congress and the Office of Management and Budget on progress with its master site plans and requirements development for consolidation by December 31, 1989."	The agency is working closely with GSA to develop requirements and other information needed to plan new facilities. Meetings with GSA staff have been held as recently as late December, and a report on the status of this work will be transmitted to the Committees in the near future.

STATEMENT OF PURPOSE

The mission of the Food and Drug Administration is to ensure that (1) food is safe, pure, and wholesome; (2) cosmetics are safe; (3) human and animal drugs, biological products, and therapeutic devices are safe and effective; and (4) radiological products and use procedures do not result in unnecessary exposure to radiation.

Under the Foods program, FDA sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food-borne disease, to determine specific health impacts of hazardous substances in foods and to develop methods for detecting them in foods; and maintains surveillance over foods through plant inspections, laboratory analyses, and legal action where necessary.

The Drugs program includes the premarket review of human drugs and biological products in order to ensure their safety and efficacy, and the post-marketing monitoring of drug experience. FDA conducts manufacturer inspections and sample examinations to ensure industry compliance. Included under this program activity is the similar regulation of animal drugs, devices, and feeds as well as a program to assure the safety of animal-derived human foods.

The Devices and Radiological Products program conducts premarket review and postmarket surveillance of medical devices to determine their safety and efficacy, and sets standards for the manufacture and use of radiological products to protect the public from unnecessary exposure to radiation. FDA monitors experience with medical devices, and conducts inspections of manufacturing plants and tests of radiological products to ensure compliance with regulations and standards.

For these three major product-oriented programs, the Agency utilizes a wide variety of scientific skills to deal with the many types of products regulated and the many scientific decisions FDA must make. These skills range from field investigators, all of whom must have education in the physical or biological sciences, to chemists, microbiologists, engineers, medical officers and scientists from many other disciplines. Similarly, FDA utilizes a variety of laboratory facilities, both to test products for safety and to conduct the research necessary to evaluate health hazards and to develop the means to detect product hazards and prevent them.

In addition, the National Center for Toxicological Research in Jefferson, Arkansas, serves as a specialized resource for FDA's other program elements by advancing the science of toxicology. This facility conducts research to improve the base of scientific knowledge on which the Agency makes decisions in assessing the risks of potentially toxic substances.

DESCRIPTION OF FIELD ACTIVITIES

FDA's Field workforce, which comprises nearly 40 percent of FDA's total staffing, performs inspections, sample collections and analyses, and initiates enforcement actions. This workforce not only conducts regular surveillance over regulated products but also serves as the critical response capability when the Agency must respond to crises and immediately investigate reports of product problems, such as tampering incidents. Both the field and headquarters are involved in informing business firms and consumers about FDA-related topics, and in working with State and local agencies to develop programs that make the best use of Federal, State, and local resources in protecting the public health.

FDA's Field force conducts investigational and laboratory functions for all of FDA's major product areas--Foods, Human Drugs, Biologics, Animal Drugs & Feeds, and Medical Devices and Radiological Products. With a highly-trained staff versed in all of FDA's product responsibilities, the Agency can respond rapidly to various types of emergencies, and can also redirect Field efforts from time to time during the year among FDA's different programs, as inspection and product testing needs change.

Field facilities include Regional Offices, District Offices and laboratories, and resident posts. The six Regional Offices are staff offices which coordinate FDA activities, and also coordinate with State authorities, in the six FDA regions. The 21 District Offices serve as offices for investigators and compliance action staff, and are the main control point for day-to-day operations in their assigned areas. The 18 District Laboratories provide FDA's basic field product testing capability. In addition, a number of these laboratories serve as specialized facilities for certain important types of testing and research.

In addition to these facilities, FDA maintains over 130 resident posts distributed widely throughout the nation. These are smaller offices which serve as a base for investigators, so that FDA can have investigative staff widely dispersed to respond to emergencies, as well as to save inspectional travel costs and time.

With all of these Field facilities combined, FDA maintains offices and staff in 48 of the States, and in the District of Columbia and Puerto Rico. (List of FDA facilities follows.)

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

Location	Activities
Washington, D.C. area:	
Rockville, Maryland	FDA Headquarters and headquarters operations of the Drugs, Devices & Radiological Products programs, and Device & Radiological laboratories
Washington, D.C.	Foods program headquarters and laboratories
Bethesda, MD	Human Drugs and Biologics laboratories
Rockville, MD	Medical Device program offices
Beltsville, MD	Foods and Veterinary Medical research facilities
Field Operations Facilities:	
Stoneham, MA	District Office
Brooklyn, NY	Regional Office, District Office and laboratories
Buffalo, NY	District Office and laboratory
San Juan, PR	District Office and laboratory
West Orange, NJ	District Office
Philadelphia, PA	Regional Office, District Office and laboratory
Baltimore, MD	District Office and laboratory
Nashville, TN	District Office
Orlando, FL	District Office
Atlanta, GA	Regional Office, District Office and laboratory
Chicago, IL	Regional Office, District Office and laboratory
Cincinnati, OH	District Office and laboratory (special emphasis in elemental analysis testing)
Detroit, MI	District Office and laboratory (special emphasis in pesticide and industrial chemical testing)
Minneapolis, MN	District Office and laboratory (special emphasis in microbiological testing)
Dallas/Houston, TX	Regional Office, District Office and laboratory
New Orleans, LA	District Office and laboratory (special emphasis in natural toxins testing)
Kansas City, MO	District Office and laboratory (special emphasis in total diet analysis)
Denver, CO	District Office and laboratory (special emphasis in animal drug residue testing)
San Francisco, CA	Regional Office, District Office, and laboratory
Los Angeles, CA	District Office and laboratory
Seattle, WA	District Office and laboratory (special emphasis in seafood products testing)
Other Specialized facilities:	
Jefferson, AR	National Center for Toxicological Research
Cincinnati, OH	Foods research laboratory in food technology and microbiology (CFSAN)
St. Louis, MO	Specialized human drug product testing laboratory (CDER)
Dauphin Island, AL	Fishery research (CFSAN)
North Kingstown, RI	Specialized facility for shellfish field surveys (CFSAN)
Winchester, MA	Winchester Engineering and Analytical Center (testing of medical devices and radiological products) - also provides general laboratory services to Stoneham, MA District Office

TOTAL RESOURCES AVAILABLE

	1989 Actual		1990 Estimate		1991 Estimate	
	$000	FTE	$000	FTE	$000	FTE
Program Expenses [1]....	$542,406	7,228	$599,066 [5]	7,692	$527,997	8,259
FDA Contingency Fund...	---	---	1,975	---	---	---
Parklawn Computer Center [2]...........	---	106	---	120	---	120
Revolving Fund for Certification and Other Services [3]....	3,129	44	3,171	45	3,338	45
Advances and Reimbursements................	6,912	20	7,168	20	164,343 [4]	20
TOTAL..............	$552,447	7,398	$611,380	7,877	$695,678	8,444

[1] Includes Buildings and Facilities.

[2] Personnel within the Parklawn Computer Center are administratively assigned to FDA. However, the Center is financed through a revolving fund, and is supported entirely by charges for services to the agencies using the Center.

[3] FDA certifies batches of insulin and of color additives used in foods, drugs, medical devices, and cosmetics. These services are financed wholly from fees paid by the industries affected.

[4] Includes $157,175,000 from projected user charges.

[5] Includes Supplemental request of $13,900,000 to be funded by user fees.

AUTHORIZING LEGISLATION

Authorizing Legislation	Type of Legislation	1989 Actual $000	1990 Estimate $000	1991 Estimate $000
Federal Food, Drug, and Cosmetic Act.........	Indefinite	$475,313	$524,907	$613,101
Fair Packaging and Labeling Act.............	"	107	122	130
Import Milk Act............	"	5	5	5
Import Tea Act............	"	130	140	145
Public Health Service Act..	"	66,851	75,867	71,791
TOTAL		$542,406	$601,041 [1]	$685,172

[1] Includes requested Supplemental of $13,900,000.

OBLIGATIONS BY OBJECT CLASS
(in thousands of dollars)

	1989 Actual	1990 Estimate	1991 Estimate
Personnel Compensation:			
Total Personnel Compensation.....	$279,606	$310,856	$358,014
Personnel benefits..............	49,836	54,928	63,180
Benefits for former personnel....	4	10	10
Total Personnel, Compensation and Benefits...............	$329,446	$365,794	$421,204
Other Objects:			
Travel and transportation of persons......	$11,596	$13,866	$14,960
Transportation of things.........	1,534	1,729	2,037
Standard level user charges......	25,612	25,612	25,612
Rental payments to others........	2,068	4,161	4,394
Rent, communications, and utilities.......................	15,200	18,146	21,465
Printing and reproduction........	2,955	3,453	3,812
Contracts and other services.....	79,447	95,219	121,245
Supplies and materials...........	17,919	21,530	24,537
Equipment........................	22,362	28,332	32,262
Grants, subsidies, and contributions...........................	9,991	11,738	12,450
Insurance claims, and indemnities	959	1,136	1,194
Construction	22,500	---	---
Total, Other Objects........	$212,143	$224,922	$263,968
Total Direct, Obligations.............	$541,589	$590,716 1/	$685,172
Unobligated balance lapsing...........	($63)	---	---

1/ Includes supplemental request of $13.9 million, to be collected from user fees, for Generic Drug activities.

ESTIMATES FOR ADVISORY AND ASSISTANCE SERVICES

	Obligations ($000)		
	1989	1990	1991
Total Consulting and Related Services (As defined by OMB Circular A-120)	$2,603	$2,700	$2,770

FDA uses consulting and related services to obtain expertise which is not feasible to maintain on the permanent staff. Because of the broad range of products that FDA regulates and the complexity of skills needed to evaluate them, it is essential for the Agency to call upon a variety of experts in academia and the private sector in order to ensure that Agency decisions are based on the best available scientific advice. In addition, experts from specialized disciplines advise both headquarters and field offices on both health issues and the latest laboratory methodology. Contractual services also assist in gathering a range of opinion for Agency decision-making, through such means as surveys and economic analyses. It should be noted that these services comprise only about one-half of one percent of FDA's operating budget. To retain on permanent staff the expertise available through consultants would be far more costly.

All of FDA's major programs utilize consulting services in varying degrees for special needs as they arise. Appointive consultants are essential for providing scientific input from a variety of sources into the Agency's regulatory decisions. Other appointive consultants include expert advisors with specialized knowledge, not available within the permanent staff, who assist in maintaining up-to-date laboratory and inspection practices. In addition, standing Advisory Committees, such as the Anti-infective Drugs Advisory Committee, are essential to provide expert opinion on both new drugs and on problems encountered with marketed drugs. Medical Device Advisory Committees, the Respiratory and Nervous System Devices Panel, are specifically required by the 1976 Medical Device Amendments. Contract services are used to obtain a range of scientific expertise on key problems in such areas as nutrition and food safety.

ADVISORY AND ASSISTANCE SERVICES

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Salaries and Expenses

(In Thousands of Dollars)

Account Title and Symbol		1989	1990	1991
Salaries and Expenses:				
I. Contractual Services				
Individual	B.A.	272	300	300
Experts &	Oblig.	272	300	300
Consultants	Outlays	244	270	274
Studies,	B.A.	1,034	1,500	1,550
Analyses &	Oblig.	1,034	1,500	1,550
Evaluations	Outlays	930	1,350	1,404
Management &	B.A.	339	300	300
Professional	Oblig.	339	300	300
Support Svcs.	Outlays	305	270	270
Engineering	B.A.	500	100	100
& Technical	Oblig.	500	100	100
Services	Outlays	450	90	90
Subtotal	B.A.	2,145	2,200	2,250
	Oblig.	2,145	2,200	2,250
	Outlays	1,929	1,980	2,038
II. Personnel	B.A.	323	350	360
Appointments	Oblig.	323	350	360
	Outlays	323	350	360
III. Advisory	B.A.	135	150	160
Committees	Oblig.	135	150	160
	Outlays	135	150	160
TOTAL	B.A.	2,603	2,700	2,770
	Oblig.	2,603	2,700	2,770
	Outlays	2,387	2,480	2,558

PROGRAM EXPENSES
TABLE OF
ESTIMATES AND APPROPRIATIONS

YEAR	Budget Estimate To Congress	House Allowance	Senate Allowance	Appropriation
1981	322,670,000 1/	319,535,000	322,670,000	321,035,000
1982	336,032,000 2/	336,032,000	328,032,000	328,032,000
1983	356,163,000	349,130,000	349,130,000	349,130,000 3/
1984	382,483,000 4/	382,004,000	386,574,000	382,574,000 3/
1985	392,554,000 4/	394,262,000	398,144,000	409,694,000 3/
1986	417,400,000 4/	418,258,000	425,517,000	420,306,000 3/5/
1987	429,225,000 4/	435,167,000	436,430,000	436,430,000 3/
1988	454,804,000 6/	476,116,000	488,604,000	476,116,000 3/
1989	507,456,000 7/	502,381,000	494,755,000	518,456,000 3/8/
1990	412,792,000 9/	582,733,000	619,733,000	585,883,000 3/ Sequestor $7,092,000
1991	527,997,000 10/			

1/ Revised budget estimate; original request was for $332,799,000.

2/ Revised budget estimate, original request was for $352,974,000.

3/ Includes Rental Payments to GSA (Standard Level User Charges) which was established as a separate account for $18,942,000 in 1983; $22,164,000 in 1984; $26,072,000 in 1985; $25,888,000 in 1986; $24,627,000 in 1987; and $25,612,000 in 1988, 1989, and 1990.

4/ Does not include Buildings and Facilities, which was appropriated as a separate account 1984, 1985, 1986 and 1987. 1986 estimate includes Budget Amendment of $9,778,000 to restore 5% pay cut. 1987 estimate includes Amendments of $5,625 which were included in the appropriations.

5/ Appropriated amount includes $18,073,000 which was subsequently sequestered.

6/ Not including Buildings & Facilities (see next page). This total includes Amendments of +$8,880 million for AIDS and -$2,357 million for reduced FERS Agency contribution rate.

7/ Does not include Buildings and Facilities, appropriated as a separate account. Includes funding of $40,420,000 for AIDS-related work which was proposed to be funded in the AIDS Research and Education account but was appropriated in this account.

8/ Not including $5,000,000 added in the Anti-Drug Abuse Act.

9/ Includes $1,450,000 for Buildings and Facilities and $25,612,000 for Rental Payments to GSA, and planned funding of $56,941,000 which was included in the proposed National HIV Program account.

10/ Includes $4,752,000 for Buildings and Facilities, $25,612 for Rental Payments to GSA, and $63,236 for AIDS.

BUILDINGS AND FACILITIES
TABLE OF
ESTIMATES AND APPROPRIATIONS

YEAR	Budget Estimate To Congress	House Allowance	Senate Allowance	Appropriation
1981	29,663,000	28,253,000	28,253,000	28,253,000
1982	--- 1/	---	---	---
1983	---	---	---	875,000 2/
1984	3,450,000 3/	4,875,000	5,875,000	18,742,000 4/
1985	1,450,000 3/	1,435,500	1,450,000	1,450,000
1986	1,450,000 3/	1,450,000	1,450,000	1,441,000 5/
1987	1,450,000 3/	1,879,000	1,879,000	1,879,000
1988	1,450,000 3/	1,450,000	1,450,000	1,450,000
1989	26,450,000 3/	23,710,000	25,736,000	23,950,000
1990	1,450,000 3/	6,950,000	12,250,000	8,350,000
1991	6/			

1/ Revised budget estimate; initial request was $15,000,000.

2/ $875,000 appropriated in the Jobs Bills Supplemental Appropriations.

3/ Funding of facilities projects in 1984, 1985, 1986, 1987, 1988, 1989, and 1990 was included in the Program Expenses request but appropriated in this account.

4/ Includes $4,875,000 in the initial 1984 Appropriation and $13,867,000 by a Supplemental Appropriation.

5/ Appropriated amount includes $62,000 which was subsequently sequestered.

6/ $4,752,000 for Buildings and Facilities projects is included in the Program Expenses request for 1991.

FULL-TIME AUTHORIZED POSITIONS BY GRADE AND LOCATION (SALARIES AND EXPENSES)

	1989			1990			1991		
Grade	Metro D.C. Area	Outside D.C.	Total	Metro D.C. Area	Outside D.C.	Total	Metro D.C. Area	Outside D.C.	Total
ES-5.......	3	0	3	3	0	3	3	0	3
4.......	51	8	59	51	8	59	51	8	59
3.......	10	6	16	10	6	16	10	6	16
2.......	8	4	12	8	4	12	8	4	12
1.......	8	2	10	8	2	10	8	2	10
Subtotal...	80	20	100	80	20	100	80	20	100
GS-16.......	1	0	1	1	0	1	1	0	1
GS/GM-15....	249	39	287	249	40	289	249	40	289
14....	517	116	633	527	118	645	533	119	652
13....	1,047	398	1,445	1,080	426	1,506	1,111	471	1,582
GS-12.......	400	613	1,013	417	672	1,089	435	749	1,184
11.......	255	430	685	278	479	757	300	546	846
10.......	5	11	16	5	11	16	5	11	16
9.......	212	185	397	230	211	441	246	249	495
8.......	77	44	121	81	44	125	81	44	125
7.......	353	272	625	367	324	691	381	394	775
6.......	226	155	381	235	164	399	244	175	419
5.......	254	262	516	266	325	591	278	406	684
4.......	129	117	246	138	124	262	147	131	278
3.......	50	17	67	53	22	75	56	26	82
2.......	19	7	26	20	8	28	20	8	28
1.......	1	0	1	0	0	0	0	0	0
Subtotal....	3,795	2,666	6,461	3,471	2,968	6,915	4,087	3,369	7,456
Commissioned Officers	363	92	455	373	92	465	388	92	480
Ungraded....	71	74	145	71	74	145	71	74	145
Total Permanent Positions...	4,309	2,852	7,161	4,471	3,154	7,625	4,626	3,555	8,181

DISTRIBUTION OF RESOURCES

	1989		1990		1991	
	$000	FTE	$000	FTE	$000	FTE
Foods						
Foodborne Biological Hazards	$ 50,912	857	$ 61,450	887	$ 85,252	1,112
Molecular Biology and Natural Toxins: Foods and Cosmetics	9,327	157	10,442	157	12,005	167
Pesticides and Chemical Contaminants	30,773	518	36,087	523	44,634	588
Diet/Toxicity Interaction	4,040	68	4,523	68	5,365	73
Postmarket Surveillance and Epidemiology: Foods and Cosmetics	1,545	26	1,730	26	1,852	26
Technical Assistance: Foods and Cosmetics	11,525	194	12,903	194	13,811	194
Food and Color Additive Petition Review and Policy Development	12,415	209	13,899	209	14,877	209
Risk Assessment Research and Policy Development: Foods and Cosmetics	4,693	79	5,254	79	5,624	79
Food Composition, Standards, Labeling, and Economics	11,941	201	13,367	201	14,308	201
Cosmetics and Color Technology	4,040	68	4,523	68	4,841	68
TOTAL, FOODS	$141,211	2,377	$164,178	2,412	$202,569	2,717
Human Drugs						
New Drug Evaluation	$ 38,621	587	$ 42,994	653	$ 50,353	706
Orphan Drugs	6,534	18	8,691	18	9,012	18
Generic Drug Evaluation	15,988	243	25,102	335	34,713	389
Over-the-Counter Drug Evaluation	3,816	58	3,853	58	4,096	58
Biopharmaceutics	5,329	81	7,141	96	10,456	119
Drug Quality Assurance	42,372	644	51,046	738	56,803	765
Bioresearch Monitoring	8,882	135	9,210	139	9,981	141
Health Fraud	2,698	41	3,027	46	3,409	48
Postmarketing Surveillance and Epidemiology	5,527	84	5,823	88	6,381	90
Prescription Drug Advertising and Labeling	1,448	22	1,462	22	1,554	22
TOTAL, HUMAN DRUGS	$131,215	1,913	$158,349	2,193	$186,758	2,356
Biologics						
Blood and Blood Products	$32,478	362	$34,668	385	$36,810	395
Viral and Rickettsial Products	15,880	177	17,938	222	20,429	242
Bacterial and Allergenic Products	11,036	123	11,551	123	12,473	129
Bioresearch Monitoring	1,077	12	1,215	15	1,441	17
TOTAL, BIOLOGICS	$60,471	674	$65,372	745	$71,153	783
Animal Drugs and Feeds						
Pre-Approval Evaluation	$10,868	184	$12,775	225	$13,847	225
Post-Approval Monitoring	13,584	230	14,281	230	16,833	242
TOTAL, ANIMAL DRUGS AND FEEDS	$24,452	414	$27,056	455	$30,680	467

	1989		1990		1991	
	$000	FTE	$000	FTE	$000	FTE
Devices & Rad. Products						
Monitoring and Quality Conformance	$37,955	611	$42,440	633	$47,188	651
Product Evaluation................	21,866	352	23,600	352	26,602	367
Education and Assistance..........	10,126	163	11,264	168	12,177	168
Bioeffects Analysis, Test and Measurement Development..........	8,510	137	9,856	147	11,815	163
TOTAL, DEV. & RAD. PRODUCTS..	$78,457	1,263	$87,160	1,300	$97,782	1,349
National Center for Toxicological Research........................	$25,545	239	$26,792	239	$27,885	239
Program Management................	31,430	348	36,197	348	37,981	348
Contingency Fund..................	---	---	1,975	---	---	---
GSA Rent..........................	25,612	---	25,612	---	25,612	---
Buildings and Facilities..........	23,950	---	8,350	---	4,752	---
TOTAL..................	$542,343 1/	7,228	$601,041 2/	7,692	$685,172	8,259

1/ Includes $5,500,000 obligated from the Contingency Fund for AIDS-related work (as appropriated to this Fund during 1988). Excludes $63,000 unobligated balance lapsing.

2/ Includes supplemental request of $13,900,000, to be collected from user fees, for Generic Drug activities.

FOODS

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
Foods				
$000	$141,211	$164,178	+$38,391	$202,569
FTEs	2,377	2,412	+305	2,717
User Charges (Proposed Legislation)				- 18,075
Budget Authority Requested				$184,494

EXPLANATION OF PROGRAM

The two paramount objectives of the Food and Cosmetics program are to assure: 1) that the nation's food supply is safe, wholesome, sanitary, and honestly labeled; and 2) that cosmetics are safe and properly labeled. The first objective encompasses a broad range of compliance, regulatory, research, petition review, education, and technical assistance responsibilities. In order to assure the effectiveness of its compliance activities, the Agency must frequently reassess its strategy for conducting surveillance of approximately 67,000 food processing plants, food repackers, warehouses, and other food operations. While FDA encourages voluntary compliance, it also must rely on regulatory actions, such as seizures, injunctions, and import detentions to take quick actions against products which are hazardous or conditions which are found to be violative. The Agency extends it capacity to conduct surveillance of the nation's food supply through contracts with states to conduct inspections within their boundaries and through cooperative agreements with state governments, local governments, and industry for milk, shellfish, and retail food service operations.

This Program's research activities are designed to support and improve the effectiveness of its compliance and regulatory activities. A large share of its research effort is devoted to developing and improving analytical methodologies needed to more rapidly and accurately detect and identify foodborne hazards; determining specific health impacts of hazardous substances in determining specific health impacts of hazardous substances in foods; developing model systems and scientific data bases required to more effectively assess risk associated with foodborne hazards; and assessing the nutrient content and quality of foods.

Through the premarket approval process, food and color additives are subjected to rigorous scientific evaluation before they may be marketed, in order to assure their safety. This assurance of safety must be established whether the substance is intentionally added to foods for some intended technical effect, inadvertently added as a result of contact with packaging materials, or become a part of the food through some other means.

Through education and technical assistance activities, consumers and industry are provided information on the hazards associated with foods, proper sanitation practices for foods, and food nutrient content and quality. Specific activities in this area include the development of labeling requirements for foods, the development and evaluation of consumer education materials, and the dissemination of information to consumers and industry concerning food safety and regulatory issues.

With regard to economic concerns, FDA develops, issues, and enforces food standards as well as other regulations which are designed to provide consumers assurance that the labeling on foods they buy is not false or misleading. Through its compliance activities, this program monitors the food supply to determine if there are products which are deceptively constituted, improperly labeled, or otherwise economically adulterated.

FDA also seeks to prevent unsafe and deceptively labeled and packaged cosmetics from reaching consumers. This is accomplished primarily through analytical method development and health hazard research, plant inspections, wharf examinations, consumer complaint investigations and voluntary registration of cosmetic products and product ingredients. Because there are no legislative requirements for pre-market approval of cosmetics or cosmetic ingredients, data gathered through these sources are essential to Agency efforts to assess the safety of cosmetic products.

Program Activity Data

Program Output	FY89 Actual	FY90 Estimate	FY91 Estimate
Food Safety:			
Food and Color Additive Petitions...	170	170	170
Food Safety Inspections:			
FDA Direct.......................	7,568	11,100	14,225
Contract.........................	7,766	7,800	7,800
Food Economics Inspections..........	283	375	375
Cosmetics Inspections...............	245	725	725
Wharf Examinations & Import Sample Collections......................	90,844	62,200	64,600
Food Safety Sample Examinations:			
Domestic.........................	19,690	16,000	19,000
Import...........................	29,466	29,000	31,500
Food Economics Sample Examinations..	1,551	1,330	1,350
Cosmetics Sample Examinations.......	691	500	500

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $12,716,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $3,754,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $1,746,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $1,864,000 and $2,803,000 is needed for the cost of relocating six field offices. Costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $2,549,000 due to inflation.

Nature of Change. An increase of $12,716,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

(2) An increase of $6,600,000 and 75 FTEs to restore FDA's Field capabilities.

Need for Change. FDA has to devote 400 to 500 FTEs each year to cope with unanticipated emergencies. Before the staffing reductions of the 1980's, FDA could cope with these extraordinary demands on the Agency and still perform essential routine inspections of the many facets of the regulated industry. Since these reductions, however, in coping with emergencies, FDA has found it necessary to delay scheduled mandatory inspections of drug and device manufacturing plants and blood banks, reduce the number of food establishment and import inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products. As an example of how reducing Field surveillance can lead to problems in the future, a number of years ago, FDA reduced inspections of blood banks to once every two years. With the increased complexity of AIDS and other screening tests and much more complicated donor screening procedures, it was discovered, in 1988, that there were significant problems in blood bank quality control procedures. Now FDA is having to respond with at least annual inspections and other intensive efforts to assure the public of a safe blood supply. As another example, FDA had virtually stopped all condom inspections in the early 1980's and only reinstated them in 1986 after the AIDS epidemic caused increased concern. There are just too many areas where routine FDA inspections have been sharply reduced or eliminated.

An aging analysis has shown that 47 percent of the Field's laboratory equipment is at or beyond the point of needing to be replaced. An increase of over $14 million would be needed to accomplish replacing all of this equipment in one year.

Nature of Change. To restore essential Field capabilities, this requires includes $6,600,000 and 75 FTEs for the Foods program.

Even if the current rate of emergency problems were to decline in the near future, FDA would still need to restore its Field resources to sustain reasonable levels of surveillance over the many products FDA regulates, and to deal with lesser problems than the major crises that occurred this year. With rising incidents of bacterial contamination in domestic and imported dairy products, the Agency is concerned about monitoring the safety of milk and other dairy products and the safety of imported foods, in view of the extreme diversion of FDA's Field capability to recurring emergency events.

Also, in order to take a phased-in approach toward replacing and modernizing the Field's laboratories, included in this request is an increase of $975,000 to replace scientific equipment that is most out of date, to bring the Field laboratories closer to maintaining a reasonable lifespan on testing equipment. This increase will not only reduce problems due to aging and obsolete equipment, but enable the Agency to take more rapid advantage of new technology as it comes on the market, greatly increasing the efficiency of our Field scientists.

(3) An increase of $3,000,000 and 25 FTEs for Forensic Chemistry Research.

Need for Change. FDA has been involved in investigating product tampering incidents for a number of years. The Tylenol incidents in 1982 and 1986 resulted in the death of a number of innocent citizens. Tampering thus became a weapon for either random killings or targeted homicides. Until recently the tampering episodes under FDA jurisdiction were confined to the U.S. and, in a majority of the cases, were localized to a particular metropolitan area. The Chilean fruit incident has now made tampering an international weapon with far reaching effects. With the exponential growth of imports, the vulnerability of U.S. citizens exposed to tampered products could also increase. As a result, the Agency must be prepared to protect the citizens when such tampering occurs.

Thus far FDA has mostly taken a reactive approach in dealing with tamperings. Namely, whenever an incident takes place, FDA conducts an investigation, initiates research, and works with various law enforcement agencies in the resolution of the incident. The Chilean fruit incident demonstrated that we do not have the luxury of initiating time consuming research when a tampering of such magnitude comes to light. In fact, the Chilean fruit incident along with a review of various FDA regulated products imported each year, suggests that FDA needs to take a proactive rather than reactive approach.

The FDA Elemental Analyses Research Center in Cincinnati, Ohio has been functioning as the Field's primary forensic laboratory on all tampering related investigations. The laboratory staff, consisting of four professionals, have not only been required to analyze samples on short notice but have also worked with the FBI, local police and other law enforcement agencies as necessary. To date, most of the tamperings have taken place with well known poisons such as cyanide, strychnine, and warfarin and the laboratory has been quick to identify the tampering agent. However, even after the poison has been identified, we need information on how specific poisons react over time in a large variety of potentially contaminated products. We had no such information in the case of the Chilean fruit episode and had to conduct research "on the fly". FDA must have the capabilities to be as proactive as possible to product tampering and such capability can only be achieved through research. Since the nucleus of a staff capability now exists in Cincinnati, this is the most logical place to locate this activity.

Nature of Change. FDA's 1991 request includes $3,000,000 and 25 FTEs to establish this increased capacity to deal with future tamperings. This laboratory will research the chemistry of a variety of potential poisons in a variety of foods, develop testing methods so that FDA can be prepared to respond when emergencies do occur, and serve as a standing body of expertise to assist other FDA offices nationwide, as well as other Federal and State agencies.

(4) An increase of $14,075,000 and 180 FTEs to expand the surveillance of seafood products and related activities.

Need for Change. Seafood is becoming an increasingly important part of the American diet. In 1987, the U.S. per capita consumption of seafood was 15.4 pounds -- up 25 percent from 1982. That same year it was estimated that U.S. consumers spent $28.8 billion for seafood products. Approximately 65 percent of all seafood currently consumed in the U.S. is imported from a total of 141 different countries. In 1988, the Agency sampled less than 3 percent of all imported seafood products.

Seafood consumed by American consumers is harvested from oceans, rivers, and lakes all over the world. In this wild, uncontrolled environment seafood may be exposed to a wide variety of biological and chemical contaminants which can render them a hazard to human health.

In recent years, the Agency has become increasingly concerned about the potential for seafood to be exposed to substances and conditions which could cause them to become a serious health hazard. This concern has been heightened by the fact that many of the products in the marketplace are the chilled or frozen products and the brown and serve varieties which often require little additional preparation before consumption. Inasmuch as many of these products will not be heated to temperatures required to destroy the most common threats to health--bacterial contaminants and parasites, additional steps must be taken to assure that the finished product is free of safety hazards and sanitation problems.

Recent reports by GAO and the Agency have highlighted a number of major concerns related to seafood products and made recommendations for improvements. The GAO report entitled Seafood Safety: Seriousness of the Problems and Efforts to Protect Consumers identified a number of specific areas for improvement. Among these are better tests for microbial pathogens and more research on chemical contaminants in seafood and human diseases caused by seafood products.

In order to evaluate aspects of its current seafood strategy and establish the basis for sound research and regulatory priorities, the Agency established a Seafood Task Force to review the size and make up of the seafood industry, identify the potential and actual health hazards related to the consumption of seafood, and assess the federal and state monitoring efforts currently in place. The Task Force report included several important findings. Among these findings were: 1) the health problems of primary concern are those associated with the consumption of raw seafood, seafood contaminated with natural toxins (e.g., ciguatera and PSP) and pathogens (e.g., Vibrio vulnificus); 2) certain segments of the seafood industry are not conforming to current good manufacturing practices in the handling of their product; 3) aquaculture as an emerging industry presents concerns related to the safe use of feed additives and drugs; and 4) industry innovations (such as modified atmosphere packaging) have a potential for public health and economic problems.

Nature of Change. An increase of $14,075,000 ($5,000,000 would result through voluntary fees under present statutory authority) will provide 180 FTEs for expanded surveillance of and research related to seafood products. Funding at this level will permit a significant expansion in domestic and import surveillance activities. In the import area the Agency will increase the number of wharf exams and the collection and analysis of import products for a wide variety of safety hazards (including microbial pathogens, pesticides, and natural toxins) and sanitation problems. In the domestic area there will be an increase in voluntary and mandatory inspections of processors, an increase in sample collections and analyses for microbial and chemical contaminants, as well as an increase in evaluations to classify seafood harvesting areas. Five million dollars of this effort is projected to be paid for by the industry, under present statutory authority, under an enhanced voluntary certification program being developed in conjunction with NOAA.

In addition, these resources will permit the Agency to expand its training and public education efforts related to seafood. For instance, FDA will provide additional technical assistance to States to help them improve their ability to classify harvesting waters and prevent illegal harvesting of seafood. Illegal harvesting currently is a major problem for State run programs. Moreover, the resources provided at this funding level will permit the Agency to expand efforts to provide consumers with information regarding the health risks associated with seafood products.

Applied research related to seafood products will be increased as well. There will be an increase in the effort to develop better testing methods for the detection of microbial pathogens, natural toxins, and chemical contaminants in seafood.

(5) An increase of $1,500,000 and 20 FTEs to support FDA's participation in the joint FDA-USDA control program for Salmonella enteritidis.

Need for Change. Since the mid-1970's, Salmonella enteritidis has become a major cause of gastrointestinal illness outbreaks in the U.S. In 1987, approximately 6,390 illnesses were attributed to this microorganism. In recent years S. enteritidis has accounted for 51 percent of all Salmonella isolates in the Northeast U.S. Although originally centered in the Northeast, outbreaks involving this microbial contaminant now have spread to the Southeast and the Mid-West and have appeared in 15 states and Puerto Rico.

In an effort to limit the spread of this Salmonella species, FDA and USDA have jointly developed and are implementing a plan of action for its control. This joint plan of action includes a flock testing program, a public awareness campaign, and cooperative research efforts to improve analytical methodologies for Salmonella.

Nature of Change. An increase of $1,500,000 and 20 FTEs will permit FDA to more effectively carry out its responsibilities under the joint Salmonella control program. Specifically it will permit FDA to increase resources devoted to the development of a rapid serological test using an antibody to detect pili -- protein antigens on the cell surface. This blood test, which is highly specific for the S. enteritidis serotype, can significantly improve the effectiveness of FDA/USDA efforts to screen poultry flocks. These resources also will permit expanded implementation of a polymerase chain reaction (PCR) method which aids in detecting S. enteritidis in animal feed, a suspected source of flock contamination.

This level of funding will also permit the expansion of the public education programs designed to make consumers aware of the proper cooking of poultry products and warn against the consumption of raw eggs and raw egg products.

(6) An increase of $500,000 and 5 FTEs to expand efforts to develop the capability to effectively analyze L-tryptophan for impurities and conduct research to determine the health hazards associated with this substance and its biological impurities.

Nature of Change. Very recent scientific evidence has established a strong and undeniable link between the consumption of L-tryptophan and the eosinophilia-myalgia syndrome, a rare blood disorder. Eosinphils are white blood cells which are believed to protect the body against worms and other parasitic organisms. When too many of these cells are produced, the body responds with a rheumatism-like illness involving aches, swollen and painful joints, fever and sometimes a rash. This condition can be life threatening.

By December of 1989, 707 cases of eosinophilia-myalgia had been reported to the CDC. Cases have been reported from all states except Alaska and South Dakota. Most of these illnesses, including at least one death, have been linked to the taking of L-tryptophan tablets, capsules and caplets. These products have been sold as food supplements and have been widely available in health food stores, supermarkets, and drug stores. Although not approved as a medical drug, it has been used by some individuals to treat sleeping difficulties, premenstrual syndrome, stress, depression as well as other problems.

FDA has requested a recall of all nonprescription food supplements in which L-tryptophan is the sole or major component and has issued an alert to detain these products at ports of entry. These actions do not apply to multi-ingredient food supplement which may have L-tryptophan as a minor component. To date none of these products have been implicated in any reported illness.

Nature of Change. An additional $500,000 and 5 FTEs will permit the Agency to improve its ability to analyze L-tryptophan and similar amino acids for biological impurities. While some manufacturers claim that their products are pure, amino acid analyses conducted by FDA indicate that some are heavily contaminated with microbial by-products. The Agency needs better screening procedures to identify and quantify these contaminants. In addition, some Agency scientists suspect that the microbial by-products are important factors in the cause of the eosinophilia-myalgia syndrome. Thus, research studies are needed to evaluate the health effects of these impurities as well as to investigate the impact of ingesting large quantities of this and similar amino acid products.

Distribution of FTEs by Project Activity

	1989 Actual	1990 Est.	1991 Est.
Foodborne Biological Hazards...........	857	887	1,112
Molecular Biology and Natural Toxins: Foods and Cosmetics..................	157	157	167
Pesticides and Chemical Contaminants...	518	523	588
Diet/Toxicity Interaction..............	68	68	73
Postmarket Surveillance and Epidemiology: Food and Cosmetics.....	26	26	26
Technical Assistance: Food and Cosmetics........................	194	194	194
Food and Color Additive Petition.......	209	209	209
Risk Assessment Research and Policy Development: Food and Cosmetics.......	79	79	79
Food Composition, Standards, Labeling, and Economics..............	201	201	201
Cosmetics and Color Technology.........	68	68	68
TOTAL, FOODS...................	2,377	2,412	2,717

EXPLANATION OF PROPOSED LEGISLATION

User Charges

In accordance with language included in FDA's Appropriations Act, the Agency is not proposing user charges under the User Charge Act (31 U.S.C. 9701). Rather, to provide for full review of proposed product review charges by the appropriate Committees of Congress, a separate legislative proposal is being submitted to authorize specific statutory authority.

While FDA's activities are designed to protect consumers, industry clearly benefits financially from regulation as well. For example, food manufacturers benefit from the assurance provided to the consumer which are created by FDA approval. Therefore, the Administration is developing a legislative proposal which would provide specific statutory authority to collect charges for these reviews. Revenues from these collections would be used to sustain the Agency's new product review processes, while reducing the need for appropriations.

HUMAN DRUGS

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
Human Drugs				
$000	$131,215	$164,178	$+28,409	$186,758
FTEs	1,913	2,193	+163	2,356
AIDS Resources				
$000	($17,005)	($19,181)	($+3,417)	($22,568)
FTEs	(208)	(222)	(+36)	(258)
User Charges (Proposed Legislation)				$-103,100
Budget Authority Requested				$83,658

EXPLANATION OF PROGRAM

The Food and Drug Administration has national responsibility for the regulation of drug products intended for human use. These products are the most frequently used therapeutic tools in the Nation's health care system. The goals of the Human Drugs program are part of the overall strategy of preventing illness, reducing health care costs and improving the health status of the public. To carry out this responsibility, the Human Drugs program has the long-range goals of assuring that the regulated products are safe, effective, and properly labeled for their intended uses in the prevention, diagnosis, and treatment of diseases, and that clinical research on investigational drugs adequately protects the rights of investigational subjects. Major objectives in support of these goals are to: (1) review and approve only those drug products that are evaluated as safe and effective under the regulations; (2) monitor the safety of drugs through programs such as the adverse drug reaction reporting system and the drug product problem reporting system; (3) effectively enforce the relevant provisions of the governing federal acts and supporting regulations through establishment inspections, sample collection and analysis, injunctions, seizures, and prosecutions; (4) develop and maintain the scientific research capability necessary to achieve greater efficiency and effectiveness in implementing the established regulations; and (5) promote informational and educational programs addressing both medical and consumer interests.

Program Activity Data

Program Output	1989 Actual	1990 Estimate	1991 Estimate
Total New Drug Application (NDA) Reviews	293	285	295
NDAs approved	79	75	75
Time from Receipt to Approval (mos.) (mean)	(29.9)	(23-30)	1/2/ (23-30)
Time from Receipt to Approval (mos.) (median)	(24.0)	(19-26)	1/2/ (19-26)
NDA Supplemental Reviews	2,427	2,300	2,300
Abbreviated New Drug Application (ANDA) Reviews	4,176	4,400	4,400
ANDA Approvals	364	450	500
Average Review Time from ANDA Receipt to Approval (mos.)	(16)	(16)	1/ (16)
ANDA Supplement Reviews	15,202	17,000	19,000
INDs (Active)	9,500	9,700	9,700
Bioequivalence Reviews	2,607	3,000	3,000
Inspections	4,211	4,900	5,300
Drug Sample Analyses	5,749	5,350	5,500
Non-clinical/Clinical Study Investigations	471	765	765
OTC Monographs Under Development	69	58	58
Adverse Reaction Report Reviews	57,106	68,000	70,000

1/ Average review times include total time from receipt to approval, including time elapsed while FDA is awaiting additional information from the sponsor.

2/ The range is dependent on success in recruitment, retention, and training. A relatively slow decrease in approval times may reflect some older NDAs in the review pipeline (which lengthens the average when they are approved) as well as the lead time necessary to train new staff before they are fully productive in the review process.

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $10,106,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $3,238,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $1,484,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $1,723,000 and $1,147,000 is needed for the cost of relocating six field offices. Costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $2,514,000 due to inflation.

Nature of Change. An increase of $10,106,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

(2) An increase of $10,200,000 and 69 FTEs to support improvements to the generic drug review process.

Need for Change. Continuation of efforts to prevent a recurrence of problems discovered in the generic drug review process. A more thorough review of ANDAs and an expanded internal quality control function will assure that generic drug applications are reviewed fairly and in accordance with sound science. Applied research activities related to generic drugs, especially bioequivalence issues will be expanded. FDA will increase the volume of samples and number of products that are selected for laboratory testing. In addition, quality assurance inspections will be conducted on generic drug manufacturers to assure that the drugs are formulated and manufactured as stated in the ANDAs.

Nature of Change. The increase of $10,200,000 will provide for 69 FTEs in headquarters and field to conduct plant inspections and laboratory analyses. It will also support the improvement of automated data systems, additional laboratory equipment, and research contracts.

(3) An increase of $2,475,000 and 33 FTEs to support improvememts to the new drug evaluation process.

Need for Change. An increasing number of the new drug applications are for new and highly complicated drug products involving increased effectiveness and benefit/risk decisions resulting from biomedical technological advances. An increase in the number of efficacy supplements is expected as more drugs being used for unlabeled indications are being submitted for approval. To evaluate these products, the FDA will need to hire additional scientific reviewers with the appropriate knowledge. Additional training for existing staff is necessary in order to continue to make the decisions on these new drug products. More scientific staff are needed to understand the pharmacokinetics and pharmacodynamics issues related to these new products.

Nature of Change. The increase of $2,475,000 will provide for hiring additional reviewers and support staff who will evaluate new drug products, conduct drug epidemiological studies, and conduct ancillary research projects to enhance the quality of the drug review process and strive for faster review of applications.

(4) An increase of $2,375,000 and 25 FTEs to restore field capability.

Need for Change. FDA has to devote 400 to 500 FTEs each year to cope with unanticipated emergencies. Before the staffing reductions of the 1980's, FDA could cope with these extraordinary demands on the Agency and still perform essential routine inspections of the many facets of the regulated industry. Since these reductions, however, to cope with emergencies, FDA has found it necessary to delay scheduled mandatory inspections of drug and device manufacturing plants and blood banks, reduce the number of food establishment and import inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products. As an example of how reducing Field surveillance can lead to problems in the future, a number of years ago, FDA reduced inspections of blood banks to once every two years. With the increased complexity of AIDS and other screening tests and much more complicated donor screening procedures, it was discovered, in 1988, that there were significant problems in blood bank quality control procedures. Now FDA is conducting at least annual inspections and other intensive efforts to assure the public of a safe blood supply. As another example, FDA had virtually stopped all condom inspections in the early 1980's and only reinstated them in 1986 after the AIDS epidemic caused increased concern. There are just too many areas where routine FDA inspections have been sharply reduced or eliminated.

An aging analysis has shown that 47 percent of the Field's laboratory equipment is at or beyond the point of needing to be replaced. An increase of over $14 million would be needed to accomplish replacing all of this equipment in one year.

Nature of Change. To restore essential Field capabilities, this request includes $2,375,000 and 25 FTEs for the Human Drugs program.

Even if the current rate of emergency problems were to decline in the near future, FDA would still need to restore its Field resources to sustain reasonable levels of surveillance over the many products FDA regulates, and to deal with lesser problems than the major crises which occurred this year. With rising incidents of bacterial contamination in domestic and imported dairy products, the Agency is concerned about maintaining the safety of milk and other dairy products and the safety of imported foods, in view of the extreme diversion of FDA's Field capability to recurring emergency events.

Also, in order to take a phased-in approach toward replacing and modernizing the Field's laboratories, included in this request is an increase of $500,000 to replace scientific equipment that is most out of date, to bring the Field laboratories closer to maintaining a reasonable lifespan on testing equipment. This increase will not only reduce problems due to aging and obsolete equipment, but enable the Agency to take more rapid advantage of new technology as it comes on the market, greatly increasing the efficiency of our Field scientists.

(5) An increase of $3,417,000 and 36 FTEs to increase efforts in AIDS activities.

Need for Change. FDA is trying to keep pace with the rising number of applications for new therapies resulting from the increase of knowledge on AIDS. We need to provide assistance to sponsors and researchers so that the safety and efficacy of potential new products acn be determined as quickly as possible. The increase will provide for continuation of expanded efforts to adopt a more active approach to facilitate therapeutics development and availability. This involves an increase in communication with sponsors from the start of preclinical studies through clinical trials, and emphasizes guidance on efficient and effective drug development and application preparation.

Nature of Change. The increase of $3,417,000 will provide for the recruitment of additional staff to conduct reviews of applications, conduct related regulatory research, provide assistance to new drug applicants about NDA requirements, and investigate increasing incidents of allegedly fraudulent products. FDA has received over 300 Investigational New Drug (IND) applications representing over 190 different products for the prevention, diagnosis, or treatment of AIDS and AIDS-related diseases. In many of these cases, FDA granted permission to begin clinical trials within five days of receiving an application. Applications continue to be received at an increasing rate. FDA must be prepared to deal with these applications as expeditiously as possible. In addition, FDA must monitor the progress of an increasing number of studies under way.

Distribution of FTEs by Project Activity

Human Drugs	1989 Actual	1990 Estimate	1991 Estimate
Biopharmaceutics	81	96	119
Bioresearch Monitoring	135	139	141
Drug Quality Assurance	644	738	765
Generic Drug Evaluation	243	335	389
Health Fraud	41	46	48
New Drug Evaluation	587	653	706
Over-the-Counter Drug Evaluation	58	58	58
Post-marketing Surveillance and Epidemiology	84	88	90
Prescription Drug Advertising	22	22	22
Orphan Drugs	18	18	18
Total	1,913	2,193	2,356
AIDS FTEs Included Above	(208)	(222)	(258)

Orphan Product Development Activities

	1989 Actual	1990 Estimate	1991 Estimate
Intramural Activities: ($000)			
Orphan Drugs Project...............	$1,134	$1,191	$1,242
Related Activities in Foods, Devices, and Radiological Products, and NCTR Programs...	966	1,014	1,058
Total, Intramural Obligations......	$2,100	$2,205	$2,300
Grants and Contracts...................	5,400	7,500	7,770
Total Obligations..................	$7,500	$9,705	$10,070
Number of Grants Awarded:			
New................................	21	35	35
Continuing.........................	40	35	35
Total number of grants............	61	70	70

1990 SUPPLEMENTAL REQUESTED FOR GENERIC DRUG ACTIVITIES

On August 18, 1989, Secretary Sullivan announced a plan to deal with the problems that had been discovered with generic drugs. This plan included increased and sustained surveillance of the generic drug industry, including both plant inspections and product testing, combined with investigations to assure the accuracy of data submitted to FDA with generic drug applications. This plan also included enhanced application review activities to assure the safety and efficacy of generic drugs, to provide thorough quality control of the process to prevent any improprieties, and to maintain prompt review by FDA; as well as the establishment of an ombudsman function to provide for resolution of disputes with firms.

As part of this plan, the Secretary announced plans to institute charges to the industry to pay for the cost of these changes within FDA. The cost of the additional resources needed for FDA in FY 1990 was estimated at $17,900,000. Final Congressional action on FDA's FY 1990 appropriations included an increase of $4,000,000 for generic drug activities, which will support 60 of the 185 additional FTEs needed to restore and sustain public confidence in generic drugs. A Supplemental Appropriation of $13,900,000 is necessary to support the additional 125 FTEs needed and provide the additional laboratory equipment and contracts necessary to sustain a sound base of product evaluation and Field surveillance over this industry.

This supplemental funding will be offset by fees to be paid by the industry. The appropriation language proposed will permit the Secretary to establish and implement fees for applications to market generic drugs and fees to holders of approved applications to support increased inspections and product monitoring. The industry will benefit from the restored public confidence in generic drugs that sustained and enhanced FDA efforts will assure. Also, the integrity and availability of generic drugs can result in savings throughout the health care delivery system, including third-party payers, especially Federal health care programs.

During FY 1989, FDA had to devote 146 Field FTEs alone to the emergency inspections and product testing of generic drugs. FDA cannot continue to divert this level of resources to this program without severe impacts on other FDA programs. As a result of generic drugs and other emergencies, FDA's inspections of regulated firms in this country continued to decline, to a level 32 percent lower than five years ago. It should be noted that although a portion of the retrospective review of the generic drug industry has been completed or is under way, FDA must continue to monitor the industry closely, and provide thorough scrutiny and investigations for new applications. FDA cannot be viewed as having done a one-time sampling of the industry and its products and then returned to business as it was before.

Although the problems discovered in this industry apply to a small number of firms and FDA's testing has not revealed widespread safety concerns with generic drugs, the problems do certainly demand a sustained increased level of surveillance over all parts of the process. For example, FDA had not previously conducted investigations to verify the validity of bioavailability studies submitted to the agency as part of generic drug applications, but this is an area where several important discrepancies have been found. The agency must establish and sustain new means to monitor this part of the evaluation process.

EXPLANATION OF PROPOSED LEGISLATION

User Charges

In accordance with language included in FDA's 1990 Appropriations, the Agency is not proposing user charges under the User Charge Act (31 U.S.C. 9701). Rather, to provide for full review of proposed product review charges by the appropriate Committees of Congress, a separate legislative proposal is being submitted to authorize specific statutory authority.

While FDA's activities are designed to protect consumers, industry clearly benefits from regulation as well. For example, new drug manufacturers benefit financially from the assurances provided to the consumer which are created by FDA approval and generic drug manufacturers will benefit as FDA is able to assure the public that their products are as safe and effective as name brands. Therefore, the Administration is developing a legislative proposal which would provide specific statutory authority to collect charges for these reviews. Revenues from these collections would be used to sustain the Agency's new product review processes, while reducing the need for appropriations.

BIOLOGICS

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
Biologics				
$000	$60,471	$65,372	$+5,781	$71,153
FTEs	674	745	+38	783
AIDS Resources				
$000	($26,595)	($28,375)	($+2,852)	($31,227)
FTEs	(170)	(182)	(+32)	(214)
User Charges (Proposed Legislation)				$-8,000
Budget Authority Request				$63,153

EXPLANATION OF PROGRAM

This program is responsible for the overall regulation of blood and blood products, bacterial vaccines and antigens, viral and rickettsial vaccines, and other biological products intended for human use. The availability of safe and effective biological products for disease prevention, treatment, or cure and the assurance of the safety of the nation's blood supply are primary public health goals. To accomplish these goals, FDA registers and inspects blood banks and other firms processing blood; licenses and inspects firms collecting human source plasma; evaluates and licenses biologics manufacturing firms and products; removes ineffective, unsafe, or improperly labeled products from the market; and reviews and improves licensing and batch control procedures while ensuring that appropriate methodology is available to assure the safety, effectiveness, purity, and potency of biologicals.

The Biologics Program provides leadership and coordination of the agency's AIDS activities and policies. Primary objectives include sponsoring and conducting AIDS-related research to foster the development of new products, regulation of AIDS products for the prevention, treatment, and diagnosis of AIDS and AIDS-related diseases, and protection of the nation's blood supply from HIV contamination.

Recent advances in biotechnology, particularly genetically-engineered organisms, have led to improved diagnostics and therapeutic treatments and to safer and more effective vaccines for the prevention of bacterial, viral, and rickettsial diseases. FDA maintains active recruitment and training programs to assure that scientific personnel have up-to-date knowledge of biotechnological techniques and methodologies. Interaction with scientists in other PHS agencies, academia, and research arms of the regulated industry is encouraged, and informational and educational programs for medical and consumer interests are promoted. FDA sponsors and conducts research, in concert with other PHS agencies, academia, and industry, to further the development of new products and to provide a sound scientific basis for their regulation.

Program Activity Data

Program Output	1989 Actual	1990 Estimate	1991 Estimate
License Application Reviews..	1,525	1,700	1,900
INDs (Active)................	2,223	2,500	3,000
IND Supplements..............	5,000	6,200	7,200
Non-clinical/Clinical Study Investigations............	48	100	100
Inspections..................	2,724	3,000	3,200

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $2,563,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990 pay raise of 3.6% on this program is $732,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $573,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $390,000 and $300,000 is needed for the cost of relocating six field offices. Costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $568,000 due to inflation.

Nature of Change. An increase of $2,563,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

(2) An increase of $2,852,000 and 32 FTEs to enhance the evaluation of AIDS and AIDS-related biological product applications.

Need for Change. FDA continues to play a vital role in the national effort to combat AIDS. To date, numerous advances have been made in combatting AIDS, resulting in an unprecedented increase in the number of applications to be evaluated. The rapid accumulation of new data and escalating clinical trials on products for use against the AIDS virus and related diseases places an increased demand on scientific and regulatory staff. During the period from 1985 to 1988, applications submitted for investigational studies of AIDS-related products have increased over 300 percent. In addition, new advances often result in more complex product issues, which frequently complicate product evaluation.

Past resource increases have not kept pace with the increasing burden placed on the biologics program by the exponential increase of AIDS and AIDS-related product applications and changes in product review regulations that require quicker, more intense review cycles and extensive interaction with manufacturers. FDA's needs include expansion of initiatives to expedite the evaluation and approval of all incoming applications for approval of therapeutic agents, increased capacity to evaluate through laboratory methods and standards, the efficacy and safety of developing candidate vaccines, expanded efforts to evaluate the increasing number of tests and other diagnostic tools for effectiveness in determining the presence of the AIDS virus and enhanced inspection efforts of blood and plasma facilities.

As part of FDA's responsibility for overseeing the safety of the nation's blood supply, a program was launched in 1988 to inspect every FDA-regulated blood bank and plasma center annually. Inspections of all 2,424 of these facilities last year revealed a number of deviations in procedures from FDA regulations. FDA's inspection program will continue to focus on procedures used by the blood and plasma industry in donor screening, testing for hepatitis and HIV antibodies, and procedures for quarantine and destruction of unsuitable blood products. These efforts will need to be increased in 1991, in order to cope with the complications associated with the use of two additional blood screening tests, to improve the rigor of quality control efforts in the inspection process, and perform additional follow-up on those establishments where improvement in their operations is needed.

Nature of Change. The increase of $2,852,000 and 32 FTEs will enable the agency to continue building the scientific research and regulatory capability necessary to expedite the review and evaluation of therapeutics, vaccines, and diagnostics products for AIDS and AIDS-related diseases.

(3) An increase of $500,000 and six FTEs to enhance serological correlates of protection and vaccine research.

Need for Change. The lack of serological correlates of protection hampers vaccine development and evaluation. This problem exists for a variety of diseases for which vaccines exist or are anticipated such as bacterial invasive diseases and certain viral illnesses. Additional research is needed to contribute to the understanding of the means by which immunologic responses can be related to vaccine efficacy. Because of adverse events associated with the administration of pertussis vaccine, the highest priority of the National Vaccine Program has been the development of new pertussis vaccines. Additional research is needed to accelerate the development of new candidate vaccines for pertussis as well as other bacterial invasive and viral diseases.

Nature of Change. The increase of $500,000 and six FTEs will enable FDA to expand its pertussis vaccine research to accelerate the development of new candidate vaccines.

Distribution of FTEs by Project Activity

Biologics	1989 Actual	1990 Estimate	1991 Estimate
Bacterial and Allergenic Products.....	123	123	129
Bioresearch Monitoring................	12	15	17
Blood and Blood Products..............	362	385	395
Viral and Rickettsial Products........	177	222	242
Total..........................	674	745	783
AIDS FTEs Included Above..............	(170)	(182)	(214)

EXPLANATION OF PROPOSED LEGISLATION

User Charges

In accordance with language included in FDA's 1990 Appropriations, the Agency is not proposing user charges under the User Charge Act (31 U.S.C. 9701). Rather, to provide for full review of proposed product review charges by the appropriate Committees of Congress, a separate legislative proposal is being submitted to authorize specific statutory authority.

While FDA's activities are designed to protect consumers, industry clearly benefits from regulation as well. For example, biologics manufacturers benefit financially from the assurances provided to the consumer which are created by FDA approval. Therefore, FDA is developing a legislative proposal which would provide specific statutory authority to collect charges for these reviews. Revenues from these collections would be used to sustain the Agency's new product review processes, while reducing the need for appropriations.

ANIMAL DRUGS AND FEEDS

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
Animal Drugs & Feeds				
$000	$24,452	$27,056	+3,624	$30,680
FTEs	414	455	+12	467
User Charges (Proposed Legislation)				-12,000
Budget Authority Requested				$18,680

EXPLANATION OF PROGRAM

This program's mission is to assure that only safe and effective animal drugs, devices, feeds, and food additives are marketed; and assure that foods from animals that are administered drugs and food additives, in accordance with label directions, are safe for human consumption.

Veterinary drugs are used to treat or prevent diseases in animals and to improve production of food-producing animals. FDA is responsible for reviewing New Animal Drug Applications to ensure that the drugs are safe and effective for animals and that food from these animals is safe before the drugs are approved for marketing. The Agency maintains continuing surveillance over all animal drugs, devices, and feeds marketed in interstate commerce to ensure their compliance with the Food, Drug and Cosmetic (FD&C) Act.

Surveillance of marketed products and agribusiness industry is accomplished through review of drug experience reports and compliance programs implemented by the FDA field offices through inspections, sample collections and analysis, investigations, and other activities. Regulatory actions are taken as needed to control violative goods and firms.

One major use of animal drugs is in animal feeds. Because of the large number of facilities subject to inspection, FDA approaches the medicated feed area through a federal/state partnership for more efficient utilization of FDA's limited resources. The Agency's medicated feed program was recently remodeled to focus attention principally on those drugs added to animal feeds which have the most potential for causing unsafe tissue residues. This has helped FDA to utilize its limited resources in a much more effective manner.

Research is another critical element in assuring the safety and efficacy of animal drugs and feed additives. Included are pharmacokinetic, toxicology, and tissue residue studies on food-producing animals as well as research to develop analytical methods, e.g., detection of drug residues in milk. Significant efforts are being directed toward research programs to provide better science for the regulation of animal drugs having a human health impact. In addition, the Agency will continue to emphasize its minor use drug research program to promote the availability of drugs for minor species and for minor uses in the major species.

Aquaculture is a new area of concern for FDA. Of particular interest to FDA is the engineering associated with farm raised fish, drug/chemical metabolism rates, use of unapproved drugs/chemicals and identification of specific disease regimens in use by the industry. FDA has issued its first assignment to begin inspections of catfish, crayfish, and trout farms.

A new workload for FDA during 1990 and 1991 will be implementation of the recent Generic Animal Drug and Patent Term Restoration Act. Although this legislation provides that applications for generic animal drugs will not be approved before January, 1991, FDA is already in the process of developing guidelines for these submissions, and establishing procedures for their review.

Program Activity Data

Program Output	FY89 Actual	FY90 Estimate	FY91 Estimate
Establishment Inspections......	1,356	1,350	1,425
Feed Mill Inspections conducted by FDA.......................	496	1,180	1,380
Feed Mill Inspections conducted by States under FDA contract..	724	750	750
Sample Analyses................	2,421	1,850	1,925
Manufacturers' Drug Experience Reports Received.............	2,565	2,700	2,700
Other Adverse Reaction Reports Reviewed......................	1,427	1,300	1,300
Medicated Feed Applications Processed.....................	5,469	4,000	4,000
Investigational New Animal Drug Applications (INADA) submissions processed..............	3,600	3,900	4,200
Total New Animal Drug Application (NADA) submissions processed.....................	2,200	2,400	2,700
Abbreviated New Animal Drug Applications Received.........	2	50	75
Full NADAs approved...........	21	24	25
Average time from Receipt to approval--original NADAs (mos.)	(30)	(30)	(30)

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $2,224,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $722,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $262,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $384,000 and $295,000 is needed for the cost of relocating six field offices. Costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $561,000 due to inflation.

Nature of Change. An increase of $2,224,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

(2) An increase of $1,400,000 and 12 FTEs to restore FDA's Field capabilities.

Need for Change. FDA has to devote 400 to 500 FTEs each year to cope with unanticipated emergencies. Before the staffing reductions of the 1980's, FDA could cope with these extraordinary demands on the Agency and still perform essential routine inspections of the many facets of the regulated industry. Since these reductions, however, to cope with emergencies, FDA has found it necessary to delay scheduled mandatory inspections of drug and device manufacturing plants and blood banks, reduce the number of food establishment and import inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products. As an example of how reducing Field surveillance can lead to problems in the future, a number of years ago, FDA reduced inspections of blood banks to once every two years. With the increased complexity of AIDS and other screening tests and much more complicated donor screening procedures, it was discovered, in 1988, that there were significant problems in blood bank quality control procedures. Now FDA is having to respond with at least annual inspections and other intensive efforts to assure the public of a safe blood supply. As another example, FDA had virtually stopped all condom inspections in the early 1980's and only reinstated them in 1986 after the AIDS epidemic caused increased concern. There are just too many areas where routine FDA inspections have been sharply reduced or eliminated.

An aging analysis has shown that 47 percent of the Field's laboratory equipment is at or beyond the point of needing to be replaced. An increase of over $14 million would be needed to accomplish replacing all of this equipment in one year.

Nature of Change. To restore essential Field capabilities, this request includes $1,400,000 and 12 FTEs for the Animal Drugs and Feeds program.

Even if the current rate of emergency problems were to decline in the near future, FDA would still need to restore its Field resources to sustain reasonable levels of surveillance over the many products FDA regulates, and to deal with lesser problems than the major crises which occurred this year. With rising incidents of bacterial contamination in domestic and imported dairy products, the Agency is concerned about maintaining the safety of milk and other dairy products and the safety of imported foods, in view of the extreme diversion of FDA's Field capability to recurring emergency events.

Also, in order to take a phased-in approach toward replacing and modernizing the Field's laboratories, included in this request is an increase of $500,000 to replace scientific equipment that is most out of date, to bring the Field laboratories closer to maintaining a reasonable lifespan on testing equipment. This increase will not only reduce problems due to aging and obsolete equipment, but enable the Agency to take more rapid advantage of new technology as it comes on the market, greatly increasing the efficiency of our Field scientists.

Distribution of FTEs by Project Activity

	FY89 Actual	FY90 Est.	FY91 Est.
Pre-Approval Evaluation...	184	225	225
Post-Approval Monitoring..	230	230	242
	414	455	467

EXPLANATION OF PROPOSED LEGISLATION

User Charges

In accordance with language included in FDA's Appropriations Act, the Agency is not proposing user charges under the User Charge Act (31 U.S.C. 9701). Rather, to provide for full review of proposed product review charges by the appropriate Committees of Congress, a separate legislative proposal is being submitted to authorize specific statutory authority.

While FDA's activities are designed to protect consumers, industry clearly benefits financially from regulation as well. For example, animal drug manufacturers benefit from the assurances provided to the consumer which are created by FDA approval. The livestock industry also benefits by FDA's assurance that animal drugs do not pose a threat to people who consume the meat. Therefore, the Administration is developing a legislative proposal which would provide specific statutory authority to collect charges for these reviews. Revenues from these collections would be used to sustain the Agency's new product review processes, while reducing the need for appropriations.

DEVICES AND RADIOLOGICAL PRODUCTS

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
Devices & Radiological Products				
$000	$78,457	$87,160	+$10,622	$97,782
FTEs	1,263	1,300	+49	1,349
AIDS Resources:				
$000	($ 7,675)	($ 8,664)	(+$ 673)	($ 9,337)
FTEs	(94)	(101)	(+6)	(107)
User Charges (Proposed Legislation)				-16,000
Budget Authority Requested				$81,782

EXPLANATION OF PROGRAM

The Medical Devices and Radiological Products program of the Food and Drug Administration pursues two overall goals: 1) ensure the safety and effectiveness of medical devices, as provided for by the Medical Device Amendments of 1976; and 2) eliminate unnecessary human exposure to radiation from medical, industrial, and consumer products, and to optimize the results of necessary exposure, as provided for by the Radiation Control for Health and Safety Act of 1968.

Under the Medical Device Amendments and the regulatory system it created, all medical devices are classified into three categories according to the level of control necessary to ensure each device's safety and effectiveness: 1) Class I - devices that can be regulated through general controls (for example, "Good Manufacturing Practice" or GMP regulations); 2) Class II - devices for which performance standards are needed, as well as general controls; and 3) Class III - devices that require premarket approval, as well as general controls.

The safety and effectiveness of medical devices is ensured by applying general controls, such as: labeling requirements, establishment registration, listing of devices, and Good Manufacturing Practices; developing performance standards for class II devices; conducting premarket review of new devices through review of premarket notifications and premarket approval applications; monitoring experience with devices on the market; and encouraging the development of useful new devices while protecting the rights and safety of human subjects in device investigations.

Educational and informational activities are also conducted to ensure proper use of complicated medical devices. FDA is continuing to develop educational material and training programs to prevent future problems related to use of dialysis equipment. As a result of user-related problems with anesthesia/ respiratory care equipment, FDA has initiated a multi-faceted program to improve the safety of this equipment. This program includes development of educational efforts directed at manufacturers and users; and initiation of cooperative efforts with manufacturers to develop critical design review guidelines and improve product labeling.

FDA minimizes radiation exposure from medical, industrial, and consumer products by conducting epidemiological and experimental research to assess the risk from various forms and sources of radiation; developing radiation measurement instruments and methods; developing performance standards; developing guidelines for the use of radiation-emitting products; and conducting surveys to determine trends in, and the current state of, the use of radiation-emitting products.

Program Activity Data

Program Output	FY89 Actual	FY90 Estimate	FY91 Estimate
Premarket Approval Applications.......	84	110	110
Average Review Time From Date Filed to Approval (days) 1/..................	247	270	270
Premarket Approval Supplements........	810	850	850
Premarket Notifications (510(k)s).....	7,022	6,000	6,000
Average Review Time From Receipt to Approval (days)....................	82	80	80
Investigational Device Exemptions.....	241	300	300
Investigational Device Exemption Supplements........................	3,038	4,200	4,200
Device Experience Network:			
Problem Reporting Program Reports Received..........................	1,894	1,900	1,900
Medical Device Experience Reports Received..........................	15,593	16,000	16,000
Inspections..........................	3,183	4,500	4,750
Product Performance Tests - FDA Direct	2,108	1,800	1,900
Product Performance Tests - State Contracts..........................	2,648	2,400	2,400
Product Sample Analyses..............	1,295	1,950	2,000

1/ Does not include time application is returned to requester to provide additional information.

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $6,224,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $2,229,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $866,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $1,109,000 and $560,000 is needed for the cost of relocating six field offices. Costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $1,460,000 due to inflation.

Nature of Change. An increase of $6,224,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

(2) An increase of $1,475,000 and 13 FTEs to restore FDA's Field capabilities.

Need for Change. FDA has to devote 400 to 500 FTEs each year to cope with unanticipated emergencies. Before the staffing reductions of the 1980's, FDA could cope with these extraordinary demands on the Agency and still perform essential routine inspections of the many facets of the regulated industry. Since these reductions, however, to cope with emergencies, FDA has found it necessary to delay scheduled mandatory inspections of drug and device manufacturing plants and blood banks, reduce the number of food establishment and import inspections, and reduce the level of regular laboratory sample analyses to screen for contaminated products. As an example of how reducing Field surveillance can lead to problems in the future, a number of years ago, FDA reduced inspections of blood banks to once every two years. With the increased complexity of AIDS and other screening tests and much more complicated donor screening procedures, it was discovered, in 1988, that there were significant problems in blood bank quality control procedures. Now FDA is having to respond with at least annual inspections and other intensive efforts to assure the public of a safe blood supply. As another example, FDA had virtually stopped all condom inspections in the early 1980's and only reinstated them in 1986 after the AIDS epidemic caused increased concern. There are just too many areas where routine FDA inspections have been sharply reduced or eliminated.

An aging analysis has shown that 47 percent of the Field's laboratory equipment is at or beyond the point of needing to be replaced. An increase of over $14 million would be needed to accomplish replacing all of this equipment in one year.

Nature of Change. To restore essential Field capabilities, this request includes $1,475,000 and 13 FTEs for the Device and Radiological Products program.

Even if the current rate of emergency problems were to decline in the near future, FDA would still need to restore its Field resources to sustain reasonable levels of surveillance over the many products FDA regulates, and to deal with lesser problems than the major crises which occurred this year. With rising incidents of bacterial contamination in domestic and imported dairy products, the Agency is concerned about maintaining the safety of milk and other dairy products and the safety of imported foods, in view of the extreme diversion of FDA's Field capability to recurring emergency events.

Also, in order to take a phased-in approach toward replacing and modernizing the Field's laboratories, included in this request is an increase of $500,000 to replace scientific equipment that is most out of date, to bring the Field laboratories closer to maintaining a reasonable lifespan on testing equipment. This increase will not only reduce problems due to aging and obsolete equipment, but enable the Agency to take more rapid advantage of new technology as it comes on the market, greatly increasing the efficiency of our Field scientists.

(3) An increase of $1,125,000 and 15 FTEs to enhance review of new device applications.

Need for Change. The workload in FDA's medical device review program increases yearly, in terms of both numbers of applications received and complexity of technologies which must be evaluated. While FDA has made great strides in expediting new device review, the Agency is concerned that it cannot sustain this progress in the face of a burgeoning workload.

Nature of Change. FDA has initiated proceedings to call for PMAs for 31 high priority class III pre-Amendments devices. Also, to relieve unnecessary regulatory burdens on both FDA and industry, FDA needs additional staff to review petitions to reclassify devices for which experience has shown that the higher classification is no longer necessary to ensure safety and effectiveness. By reducing the number of PMAs awaiting review and approval, reclassification ultimately allows FDA more time to review new and complex medical device technologies which require premarket approval. The increase requested will provide 15 FTEs to meet these specific needs as well as strive to sustain the progress that has been made in expediting review of new devices.

(4) An increase of $525,000 and 7 FTEs to enhance risk assessment and test methods development.

Need for Change. The explosion of new device technologies has necessitated development of several new device-related laboratory research and testing programs. Additional resources are needed to keep on top of these new and changing technologies, and to expand the scientific capability for risk assessment research and test methods development. These activities are important because they enable FDA to optimize protection of the public health by focusing efforts where they are most needed and obtain data which provides a sound scientific basis for all actions involving medical devices and radiological products.

Nature of Change. FDA is requesting seven FTEs to establish and maintain comprehensive scientific competence in its biomaterials program; to expand fluid dynamics and flow related research; and additional resources will also enable FDA to keep abreast of changing program needs as well, for example, in its medical device materials program.

(5) An increase of $600,000 and 8 FTEs for medical device postmarket surveillance activities.

Need for Change. Additional resources will enable FDA to improve the quality and utility of data currently in the postmarket surveillance database and to expand the investigation of reports of death, injury, and malfunctions under the Medical Device Reporting regulation.

Nature of Change. Eight FTEs are being requested to enable FDA to integrate trend analysis into the routine Medical Device Reporting evaluations to check for increases and decreases in various types of device related problems. In addition, FDA will assess the feasibility of expanding its postmarket surveillance program by establishing a model problem reporting program among a network of teaching/research hospitals. The program would serve to educate health care professionals about the need for problem reporting and give them practical experience in reporting. In its fully operational phase, the program would create a "sentinel system," allowing FDA to test the effectiveness of hospital reporting.

(6) An increase of $700,000 and 6 FTEs for medical device AIDS-related activities.

Need for Change. FDA has an ongoing regulatory responsibility to assure the safety and effectiveness of medical devices which, in terms of prevention of AIDS and AIDS-related diseases, include barrier products, such as condoms and surgical gloves, and commonly-used clinical devices, such as dental drills and endoscopes. The AIDS epidemic has raised several new issues with respect to the regulation of these products.

Nature of Change. FDA is requesting an increase of six FTEs in an effort to increase its understanding of the effectiveness of barriers against the transmission of HIV and to expand research on the effectiveness of existing disinfectants and methods to evaluate disinfectant efficacy. Additional resources will also enable FDA to continue its enhanced evaluation program for condoms and medical gloves; to work with device manufacturers to improve device designs in ways that would facilitate disinfection/sterilization; to continue activities aimed at informing the public and health professionals about the proper use and reuse of medical devices to prevent transmission of HIV; and to promote dialogues with manufacturers and trade associations, with respect to AIDS-related device issues.

Distribution of FTEs by Project Activity

	FY89 Actual	FY90 Est.	FY91 Est.
Monitoring and Quality Conformance..................	611	633	651
Product Evaluation............	352	352	367
Bioeffects Analysis, Testing, and Measurement Development..	137	147	163
Education and Assistance......	163	168	168
	1,263	1,300	1,349
AIDS FTEs Included Above.......	(94)	(101)	(107)

EXPLANATION OF PROPOSED LEGISLATION

User Charges

In accordance with language included in FDA's Appropriations Act, the Agency is not proposing user charges under the User Charge Act (31 U.S.C. 9701). Rather, to provide for full review of proposed product review charges by the appropriate Committees of Congress, a separate legislative proposal is being submitted to authorize specific statutory authority.

While FDA's activities are designed to protect consumers, industry clearly benefits financially from regulation as well. For example, medical device manufacturers benefit from the assurance provided to the consumer which are created by FDA approval. Therefore, the Administration is developing a legislative proposal which would provide specific statutory authority to collect charges for these reviews. Revenues from these collections would be used to sustain the Agency's new product review processes, while reducing the need for appropriations.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Summary of Project Estimates
($000)

Project	1989 Actual	1990 Estimated	Change in 1991	1991 Estimated
NCTR				
$000	$25,545	$26,792	+$1,093	$27,885
FTEs	239	239	---	239

EXPLANATION OF PROGRAM

Resources identified with the Food and Drug Administration's National Center for Toxicological Research (NCTR) are used to conduct fundamental research aimed at understanding the mechanisms of action of chemical substances, their metabolism in mammals and their rates of absorption and excretion. The result of this research provides a better understanding of dose-response relationships for evaluation of genetic aberrations, birth defects, cancer, or biochemical and metabolic alterations induced in animals and their relevance to human health. The overall goal of this research effort is to improve the Agency's base of scientific knowledge on which specific risk analyses of regulated products must be founded. Research emphasis is placed on the development of valid indicators of exposure; determinations of chemical activity in biologic systems; assessment of individual differences in susceptibility to chemicals or to classes of chemicals; and extrapolation of these research findings to human exposure and health. The changes environmental chemicals cause in the basic biochemical processes at the molecular or cellular levels provide essential information on the causes and development of diseases in humans and experimental animals.

NCTR must maintain research breadth sufficient to cover the major aspects of toxicology. Through interactions between disciplines during the review stages of planning specific projects, FDA can assure more effective results by bringing the knowledge to bear on the problem at hand. Sophisticated methodology and equipment, along with enhanced collaborations, have blurred the historic organizational lines; thus FDA is finding it scientifically valuable to interact with scientists from all sectors of the research community. Rapidly moving developments in science make it critical to maintain proactive and aggressive communications with leading experts in the various fields.

The overall effort may be categorized into the following three general areas:

> Biomarkers -- Developing and evaluating biochemical procedures, including birth defects and cancers, in animal models and tissues to provide quantitative indicators of exposure to a toxic chemical or to assess individual differences in susceptibility to certain chemicals or to classes of chemicals.

Modulators of Toxicity -- Toxic chemicals change basic biochemical processes within cells. To better understand how a chemical causes those changes, it is first necessary to understand how normal physiological parameters (such as diet and caloric restriction) alter those processes. Once that is understood at the molecular level in laboratory animals and humans, the program can develop a bridge between whole animal (cancer) and molecular or cellular events.

Extrapolation/Exposure Assessment -- Addressing a number of critical assumptions which have not been adequately tested and which are used in the process of assessing risk.

The National Center for Toxicological Research is located in Jefferson, Arkansas, in facilities owned and operated directly by FDA. Many of the research, research support, and administrative functions needed to operate the NCTR are necessarily obtained through service contracts. Over 55 percent of NCTRs onsite work force is comprised of Contractor personnel.

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $1,093,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $352,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $154,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $192,000 and costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $395,000 due to inflation.

Nature of Change. An increase of $1,093,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

PROGRAM MANAGEMENT

Summary of Project Estimates
($000)

	1989 Actual		1990 Estimated		Change in 1990		1991 Estimated	
Project	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years
Prog. Mgmt. activities	$31,430	348	$36,197	348	$+1,784	---	$37,981	348
Rental Payments to GSA	25,612	---	25,612	---	---	---	25,612	---
Total Prog. Mgmt.	$57,042	348	$61,809	348	$+1,784	---	$63,593	348

EXPLANATION OF PROGRAM

This activity provides central program direction and administrative services for Agency programs to ensure that FDA's consumer protection efforts are effectively managed and that available resources are put to the most efficient use. These functions include providing agency-wide policy development in the areas of medical affairs, scientific coordination, regulatory requirements, legislation, planning and evaluation, consumer communications, and public information; and management expertise and coordination in financial management, personnel, contracts and grants administration, procurement/property/space control, and communications systems. Within this activity, several broad initiatives cut across program and organizational lines. These include providing guidance to field surveillance activities, improving agency analytical capabilities by integrating new scientific knowledge with current activities, ensuring the effectiveness and fairness of regulatory processes to industry in general, and small businesses in particular, through review of existing and proposed regulations in accordance with Executive Order 12291 and the Regulatory Flexibility Act.

Specific programs within this activity are management of Freedom of Information (FOI) activities, to respond within statutory timeframes to inquiries, and the Small Business Program, to assist small businesses in carrying out regulatory requirements and in participating in FDA's regulatory decision-making process, to minimize the economic impact of necessary Agency regulations on small businesses.

JUSTIFICATION OF INCREASES AND DECREASES

(1) An increase of $1,784,000 to offset built-in costs.

Need for Change. The full annual impact of the January, 1990, pay raise of 3.6% on this program is $703,000. Although FDA is absorbing the 1990 impact of this pay raise, an adjustment in 1991 for the full impact is needed in order to assure that FDA can meet payroll costs while at the same time providing effective support for its employees in terms of supplies, equipment, and contractual services. In addition, this request includes $223,000 which is 50 percent of the projected cost of the January 1991 pay raise. Other personnel-related costs in this program will cost $322,000, and costs of travel, supplies, contracts, equipment and other support expenses are expected to increase $536,000 due to inflation.

Nature of Change. An increase of $1,784,000 to meet these rising costs will enable FDA to sustain the current level of operations in this program.

RENTAL PAYMENTS TO GSA

Summary of Project Estimates
($000)

Project	1989 Actual Amount	1990 Estimated Amount	Change in 1991	1991 Estimated Amount
Rental Payments to GSA	$25,612	$25,612	----	$25,612

In the 1990 appropriation, Congress provided funds for rental payments to GSA at the same rate as the 1989 level of funding. The estimate for 1991 is not based on information the Agency has received from GSA as to the projected rates for each location. Instead, Congress has capped FDA's rental payment to GSA at $29,600,000 since FY88 and there is language being proposed to limit the 1990 rental payment to GSA to the 1990 level without requiring a reduction in the level of rental space and without prohibiting an expansion of rental space or services with the use of funds otherwise appropriated in the Act.

The Agency is proposing that in 1991, FDA's rent costs be included, as they were in 1982 and prior years, in the Program Management activity of FDA's Program Expenses Appropriation. The appropriation language proposed will allow for a limitation on these costs, while retaining some flexibility as provided by the Congress in recent years, without the need for a separate account. A number of factors, aside from rate changes and changes in total space, can affect rental payments. For example, in 1983 FDA leased a new laboratory facility in Chicago which was obtained under direct-lease delegation of authority from GSA. Since FDA pays the lesser directly, this reduces rental payments to GSA, but will not reduce FDA's total space costs. Also, if GSA directs FDA to relocate one of its district offices due to problems with leasing or maintaining the current facility, the total space and the cost of newly leased space could significantly affect the GSA billing.

FDA uses about 2.2 million net square feet of space covered by GSA rental charges. About 60 percent of these charges are for facilities in the Washington area, of which the largest are the Parklawn Building and Federal Building 8. The major field expenses, of course, are for the Agency's District Offices, although the Agency also has about 130 small leased offices as resident posts for field investigators, which provide significant savings in time as well as travel costs, and provide for a wide geographic dispersion of FDA staff to enable them to respond to emergency situations.

Rental costs do not apply to those facilities owned and operated by FDA, including primarily the National Center for Toxicological Research and FDA's new headquarters foods research building at Beltsville, Md., nor to facilities at NIH or the Beltsville Agricultural Research Center, for which FDA reimburses the other agencies directly for expenses incurred in operating and maintaining the facilities provided for FDA. The rental charges shown above also do not include the special services for which FDA must pay GSA on a reimbursable fee-for-service basis, such as special guard services and the provision of around-the-clock heating and air conditioning where required for FDA's laboratory work.

BUILDINGS AND FACILITIES

Summary of Project Estimates
($000)

Project	1989 Actual Amount	1990 Estimated Amount	1991 Estimated Amount
Buildings & Facilities	$23,950	$8,350	$4,752

Justification: $4,752,000 is needed to provide for continued repairs and improvement of FDA laboratories. In addition to Washington area laboratories which are in nine separate locations, there are 23 lab facilities around the country, including regular field laboratories and specialized facilities, as well as the NCTR complex. Continued repairs, modifications, and improvements to FDA headquarters and field facilities must be made to preserve the properties, ensure employee safety, meet changing program requirements, and permit the Agency to keep its laboratory methods up to date. The Agency's ability to support sound regulatory research, testing, and analysis, which are vital to assuring public health and safety, rely upon modern and optimally functioning facilities and equipment. In addition, for NCTR and some other smaller facilities which are owned and operated by FDA, the Agency must make all necessary repairs, from road repairs to replacement of utility systems when needed.

Plan of Work: The total of $4,752,000 requested will provide for the projects needed in 1991 to sustain FDA's basic operational capabilities, by assuring proper maintenance of government facilities and making limited laboratory improvements to ensure effective utilization of FDA's laboratory staffs and equipment. The work needed includes a wide variety of maintenance items such as road and roof repairs, maintenance of utility distribution systems, and minor laboratory renovations and upgrading of laboratory systems such as electrical, gas, water, and air circulation, as needed to meet changing laboratory testing needs and to support sophisticated analytical equipment.

Funding is requested for projects at the following locations:

1. Field District and specialized laboratories at eighteen locations nationwide	$2,600,000
2. National Center for Toxicological Research, Jefferson, Arkansas	900,000
3. Center for Food Safety and Applied Nutrition, Beltsville Research Facility	1,000,000
4. Center for Veterinary Medicine, Beltsville, MD	252,000
	$4,752,000

BUILDINGS AND FACILITIES

APPROPRIATION SUMMARY

	Amount $000
1989 Budget Authority................................	$23,950
1990 Appropriation...................................	8,350
Unobligated balance, start of 1990................	29,715
Unobligated balance, end of 1990..................	---
1990 Total Obligations...............................	$38,065

For 1991, $4,752,000 for Buildings and Facilities projects is included in the request for Program Expenses. The funds obligated in 1990 and prior years will remain in the separate Buildings and Facilities account until actually expended.

FOODS AND COSMETICS

STATUS OF PROGRAM

Activities of the Food and Cosmetics program are authorized under several major pieces of federal legislation, including the FD&C Act, the Public Health Service Act, the Tea Importation Act, the Fair Packaging and Labeling Act, and the Infant Formula Act. These Acts, either in their entirety or in part, give FDA major responsibilities for assuring the safety, sanitation, wholesomeness and economic value of food and the safety and proper labeling of cosmetics available to U.S. consumers. These responsibilities cover imported as well as domestically produced products.

Current Activities. In order to meet these responsibilities, FDA:

1. Inspects establishments, collects samples, analyzes samples, and takes legal action, where necessary, in order to prevent domestically produced or imported foods which may be hazardous or insanitary from entering the market place. This includes contract agreements with states under which they perform surveillance activities for some food establishments within their boundary.

2. Provides training and technical assistance to state and local governments on matters related to the design, implementation, and evaluation of retail food protection programs.

3. Prevents the introduction or transmission of communicable disease through the review and approval of food and color additive petitions. Samples and analyzes marketed food products and food contact surfaces for the presence of unapproved or excessive amounts of approved food additives.

4. Assures the safety of food additives prior to marketing through the review and approval of food and color additive petitions. Samples and analyzes marketed food products and food contact surfaces for the presence of unapproved or excessive amounts of approved food additives.

5. Maintains and improves the nutritional quality of the nation's food supply by ensuring that food products meet established nutrient requirements. This includes activities designed to assure that nutrition labeling is informative and accurate, including those intended to encourage the use of sound nutrition principles and labeling in the prevention and management of disease.

6. Conducts research to develop more rapid and accurate methods for the detection and enumeration of foodborne biological hazards.

7. Develops more effective methods for assessing health hazards associated with infant formulas, and investigates the effects of processing and formulation on the nutrient quality of these products.

8. Develops and expands single compound and multi-residue methods for the analysis of pesticides and their metabolites in foods.

9. Conducts studies to determine the levels of occurrences and daily dietary intake of pesticides, PCBs, and other industrial chemicals, selected toxic elements, nutrients, and radionuclides.

10. Develops new or amends existing food standards and other regulations that are intended to assure the fair, accurate, and honest labeling of food products. Conducts research to develop or improve analytical methods required to more rapidly and accurately detect economic adulteration in foods.

11. Conducts toxicological research studies to determine the safety of cosmetics and cosmetic ingredients as well as develop data bases to quantify the health risks involved with their use.

12. Develops and improves analytical methodologies to identify and quantify any hazardous ingredients, dangerous additives, or chemical and microbial contaminants in cosmetic products.

13. Conducts inspections and sample analyses to determine that cosmetic production facilities are sanitary and that cosmetic products are prepared, packed, and held in accordance with good manufacturing practices.

Selected Examples of Recent Progress:

1. Pathogenic Microbial Contamination

In 1989 foodborne pathogenic microorganisms again presented the most serious health concerns related to foods. While Listeria monocytogenes continued to be a leading foodborne microbial contaminant, the major illness outbreaks were attributed to other pathogens, such as Staphylococcus aureus, Salmonella enteritidis, Clostridium botulinum, and Yersinia enterocolitica.

Mushrooms: One of the most wide spread series of food poisoning incidents during 1989 involved canned mushrooms contaminated with Staphylococcus aureus enterotoxin. The first of several illness outbreaks linked to mushrooms contaminated with S. aureus enterotoxin occurred in February at Mississippi State University where 20 students became ill and nine were hospitalized after eating hamburgers or omelets containing mushrooms. FDA tests on mushroom samples from the omelet bar as well as from unopened cans associated with the incident confirmed the presence of Staphylococcus enterotoxin. Another incident occurred at the Peninsula Hospital Center cafeteria in Queens, New York where 39 people were stricken and two were hospitalized. In this incident Agency tests confirmed the presence of S. aureus enterotoxin based on the analysis of samples from unopened cans of mushrooms. A third incident occurred in Philipsburg, Pennsylvania where 20 people reportedly became ill after eating pizzas topped with mushrooms. Again FDA laboratory tests confirmed S. aureus enterotoxin in previously unopened cans of mushrooms.

Altogether the Agency was able to confirm four separate Staphylococcal food poisoning outbreaks involving over 100 individuals. In each case the manufacturing codes of the product identified the Peoples Republic of China as the country of origin. FDA's analysis of some other samples which were not directly involved in an illness incident also revealed the presence of S. aureus contamination.

FDA took several actions in response to this problem. First, it requested an immediate recall of the product implicated in each incident. It issued an import alert requiring the detention of the product at all ports of entry. The recalls and import detentions were expanded as sample analyses implicated the products of other manufacturers. Moreover, the Agency expressly prohibited the reconditioning of any container size or product styles of canned mushrooms from lots found to be contaminated.

As data from sample analyses mounted, it became clear that the S. aureus enterotoxin contamination in canned mushrooms could not be isolated to a few processors. The analytical evidence suggested that the problem was more widespread than expected and probably resulted from a breakdown of normally accepted quality assurance procedures for harvesting, processing and handling the product throughout the mushroom processing industry in the PRC. Based on this evidence, the Agency instituted a "Mushroom Control Program". Under this program an import alert was issued for the automatic detention of all canned mushrooms from the People's Republic of China, including all container sizes and styles. In addition, the Agency requested a report from the PRC within 60 days on the contamination problem. Specifically, the Agency wanted information on the factors which had caused the S. aureus enterotoxin contamination and an indication of the measures that had been implemented to correct these factors.

Botulism from garlic-in-oil: In late February, three cases of botulism were reported in Kingston, New York. These illnesses were linked to commercially prepared chopped garlic-in-olive oil which had been used in the making of garlic bread.

The Agency took several actions in response to this incident. It declared garlic-in-oil mixes which require refrigeration an "imminent hazard" because of their potential to cause fatal illness if left at room temperature. Consumers were advised to discard any garlic-in-oil product in their possession. Manufacturers, repackers, food distributors, and retailers who might handle these foods were advised to withdraw them from the marketplace and warned that any such products which remained in the marketplace might be subject to seizure or injunction actions. In addition, manufacturers were advised to reformulate these products to include microbial inhibitors, such as acidifying agents. The acidifying agents prevent the development of microbial toxins if consumers or retailers fail to maintain the product under proper refrigeration.

Salmonella in eggs: Incidents of illnesses linked to Salmonella enteritidis continued to spread. Reported illness outbreaks involving this pathogen continue to be linked primarily to the consumption of eggs and egg products and now have been reported in 15 states and Puerto Rico. Under the program jointly developed with USDA for controlling the pathogen, FDA assisted in the investigation of several food incidents involving S. enteritidis during 1989.

One was an illness outbreak which occurred in New York and involved 21 individuals, 18 of whom had to be hospitalized. The Agency also investigated the distribution of 1,000 cases of eggs from a contaminated flock in New Jersey. In another instance, FDA and USDA jointly investigated a Salmonella contamination incident involving 39,281 pounds of pasteurized liquid whole eggs distributed in Minnesota.

Raw oysters: Vibrio vulnificus has been identified as an important cause of septicaemia in the Gulf Coast Region. A CDC report on 43 V. vulnificus patients in 1988 from Alabama, Florida, Louisiana, and Texas indicated that 26 had primary septicemia, ten had wound infections, five had gastroenteritis, and two had eye infections. Twenty-four of these were identified as having underlying medical conditions, including liver disease, alcoholism, diabetes, HIV seropositivity, aplastic anemia, Hodgkin's disease, and thalassemia. In all cases where patients had provided good food histories, it was determined that they had consumed raw oysters in the seven days before onset of the illness.

2. Pesticide Surveillance

In October, the Agency issued the second annual report on its surveillance of the food supply for pesticide residues. This report, which covers 1988, explains the changes made in FDA's pesticide residue monitoring program for 1988, presents the results of FDA's pesticide residue monitoring for 1988, and compares the 1988 findings with those of 1987.

In summary, the report states that a total of 18,114 food samples were analyzed for pesticide residues in 1988. Of this total, 7,639 samples were of domestic products collected in 50 states and Puerto Rico. Another 10,474 samples were of import products taken from food shipments imported from 89 countries. No pesticide residues were found in 61 percent of the samples and less than one percent contained violative residues. Under the Total Diet Study another 1,170 samples representing typical diets of U.S. consumers in various geographical regions and various age groupings were analyzed. The levels of dietary intakes of nearly all the pesticides found were less than one percent of the acceptable intake levels set by the Food and Agriculture Organization/WHO.

In addition, the report noted that the number of detention for pesticide contamination for 1988 more than doubled those for 1987. This increase was attributed primarily to a policy change whereby an automatic detention may be invoked when only one shipment of a particular product is found to be violative.

The provisions of Pesticide Monitoring Improvements Act of 1988 give FDA new responsibilities for identifying pesticide residues on imported foods. One part of this legislation requires that FDA enter into cooperative agreements with foreign countries which import significant amounts of food to the U.S. Under these agreements the exporting countries will provide FDA with pesticide usage data for their crops. In 1989, FDA held discussions with 25 of 37 countries which export large quantities of food to this country, and each has agreed to develop the necessary information. However, the Agency cannot state at this point how many of these discussions will actually result in cooperative agreements.

3. Recalls and Regulatory Actions

Recalls and regulatory actions are the primary means through which the Agency removes hazardous and potentially hazardous products from the market place or requires the correction of conditions which might contribute to the production of hazardous or insanitary food or cosmetic products.

Although performed voluntarily by the manufacturer at the request of the Agency, recalls are one of the quickest ways to remove hazardous, insanitary, or economically deceptive products from the market place. During 1989, there were 562 recalls (527 were food related and 35 concerned cosmetic products). The food recalls covered a wide variety of products and problems in addition to those related to imported mushrooms and garlic-in-oil products. For instance, fluid milk products were recalled from retail outlets in northern Mississippi and Louisiana after it was learned that they were contaminated with low levels (1 ppm or less) of barium carbonate -- a compound once used as a rodenticide. Through reports on the deaths of 20 dairy cattle in East Texas and Western Louisiana, FDA and officials from both states were able to identify the contaminated herds. The investigation later determined that source of the contamination was soybeans which had been used to make feed which had been given the animals. The soybeans had been transported in a rail car which had not been properly cleaned after transporting a shipment of barium carbonate.

Another recall action involved flame broil prepared sandwiches contaminated with Listeria monocytogenes. This contaminant was isolated from the meat patties used to make these sandwiches. Other food products subjected to recalls were ice cream, ice milk, sherbet, egg nog, and salad dressing due to undeclared FD&C Yellow 5; chocolate Easter candy due to contamination with glass and/or plastic fragments; domestic and imported crab meat due to Listeria monocytogenes contamination; ice cream and other frozen deserts due to Listeria contamination; canned tuna due to decomposition; canned peaches from Greece which failed to comply with the standard of quality for yellow canned peaches; and ceramicware due to excessive levels of leachable lead.

In the import area, product detentions permit the Agency to take immediate action to prevent hazardous or insanitary foods and cosmetics from reaching the U.S. market place. There were a total of 29,168 detention actions in 1989. Of this total, 28,236 concerned foods and 924 concerned cosmetics. In addition to mushrooms from the Peoples Republic of China, numerous other products were the subject of detention actions in 1989. For instance, an import alert was issued to detain mahi mahi due to histamine contamination and decomposition. Swordfish from Chile were detained due to methyl mercury contamination. Ceramicware from Spain was detained due to excessive lead and cadmium levels. Low-acid and acidified products such as canned beans, asparagus, whole chestnuts, and beans in tomato sauce were among the other foods products put under detention.

4. Tampering Incidents

The most notable tampering incident involved cyanide in grapes from Chile. This incident required the diversion of over 60 Field staffyears to screen Chilean produce following the initial threat of tampering. In response to this incident the Agency undertook a number of research studies to improve its ability to react rapidly to these situations. These included studies on the dissipation of sodium cyanide after topical application to fruit, the dissipation of sodium cyanide in solution after topical application to fruit, the dissipation of sodium cyanide solution injected in fruit, and the evaluation of rapid and accurate quantitative methods for the detection of cyanide.

Several other tampering incidents occurred which involved foods. One involving a box of breakfast cereal occurred in New York state. An envelope marked "Poison" was found in the cereal box. Another incident in the Northeast involved black cherry yogurt which apparently contained cyanide. FDA requested a recall of the product and thoroughly investigated each incident. No product contamination was found in the stores where the products were sold or elsewhere in the area. In the case of the yogurt, an Agency inspection of the plant showed no cyanide contamination. Based on its investigation the Agency concluded that these were isolated events.

5. Special Field Assignments

Special field assignments supplement routine food and cosmetic surveillance activities. They permit the Agency to focus on much smaller segments of the food supply where a known or potential problem exists. Through this mechanism the Agency can assimilate the data needed to more clearly evaluate the magnitude of a foodborne health problem, collect data needed to determine the need for a regulatory initiative, or assess the impact of an existing regulation.

Over 30 field assignments were issued in 1989. Some of these were directly related to major food safety problems. For instance, one assignment covered garlic products in water and nuts or herbs in oil. Inasmuch as these products bear a close similarity to the garlic-in-oil product implicated in the botulism incident, the Agency wished to determine if these products also represent a potential hazard to health.

Another special assignment covered canned mushrooms imported from the PRC. This assignment provided critical information on the incidence and possible source of the S. aureus contamination, helped identify manufacturers of the contaminated product, and helped identify products which illegally entered this country from unregistered factories.

Dioxin in milk cartons: A field survey confirmed an earlier Canadian report that extremely low levels of dioxin (TCDD) and the less toxic furan (TCDF) migrate from bleached paperboard cartons into packaged milk. Whole milk in half pint cartons was collected at milk packaging plants in various locations of the U.S. in early 1989. All five companies that produce paperboard packaging for milk products were represented in the survey. The analytical results confirmed that TCDD and TCDF can migrate in extremely low amounts to milk from the chlorine-bleached, polyethylene-coated paperboard cartons. After becoming aware of these findings, the paper industry initiated efforts to modify its production methods in order to substantially reduce dioxin and furan levels in bleached paper products. By the end of the Fiscal Year, the American Paper Institute had informed FDA that the majority of paperboard for milk cartons were already being produced by modified production methods. This organization also reported that the remaining firms have the new technology on order. The very low residue levels found will not pose a threat to health while the change is being completed.

6. Analytical Method Development

The Agency continually strives to improve the effectiveness of its surveillance activities through the development of faster and more accurate analytical methods for contaminants in foods and cosmetics. Several significant accomplishments were achieved in this area during the past year. One of these was the development of several polymerase chain reaction (PCR) methods for the detection of several viruses, including rotaviruses, the Norwalk viruses, and Hepatitis A. A PCR method also was developed for *S. enteritidis* in feed, a suspected source of poultry flock contamination. These accomplishments are particularly significant because PCR methods are very rapid, specific, sensitive, and practical. Moreover, since they amplify the contaminant that is present in the food, they provide an effective means of detecting these substances when only very small amounts are present.

Another important accomplishment was the successfully development of the agarose-gel electrophoretic method for differentiating between bovine and microbial phosphates. Because this method is able to make this distinction, alkaline phosphates can be used to determine if unpasteurized milk has been used in the production of cheese. The Agency believes that the use of unpasteurized milk is a leading cause of microbial contamination in cheese products.

The Agency also developed a post-column system that may provide a more effective means for quantitating previously undetectable N-nitroso compounds in foods. Moreover, in order to conduct work to determine the levels of dioxin (TCDD) and furan (TCDF) in milk cartons, existing Agency methods had to be modified to detect these contaminants at concentrations far below the 1 part per trillion (ppt) level.

7. National Center for Food Safety and Technology

FDA continued its efforts to develop the new National Center for Food Safety and Technology in Chicago. This cooperative biotechnology laboratory involving the Illinois Institute of Technology, the IIT Research Institute, the University of Illinois and FDA will contain 200,000 square feet of laboratory space and is uniquely suited for fermentation research. Because this is a consortium composed of industry, academe, and government entities, work at this facility will focus on research into food safety and quality issues that are too large and too diverse for any one sector of the food industry to tackle alone. By facilitating cooperation, research, and information exchange among these groups, the Agency seeks to take a systematic and interdisciplinary approach to potential food safety issues before they become a crisis.

8. Improved Inter-Agency Relationships

FDA has pledged to strengthen working relationships with other government agencies which have responsibilities related to the safety of foods and cosmetics. Among the specific agencies FDA has attempted to develop better working relationships with the U.S. Customs Service, the Consumer Product Safety Commission, the Environmental Protection Agency, the U.S. Department of Agriculture, and the National Marine Fisheries Service. Through improved relationships with these agencies, FDA hopes to minimize duplications in efforts and work cooperatively to improve the safety and quality of products available to U.S. consumers.

Concrete examples of improved interagency relationships are seen in several Memos of Understanding (MOUs) FDA signed with other agencies during 1989. One of these MOUs was signed with USDA's Animal and Plant Health Inspection Service (APHIS). Under this agreement FDA will contract the services of the APHIS Gulfport laboratory to analyze food samples for pesticide residues. This will help FDA to significantly increase the number of food samples analyzed each year for pesticide residues.

Another Memo of Understanding was established with USDA's Extension Service. The food portion of this agreement is designed to promote cooperative efforts to educate and inform the U.S. population on basic food safety and nutrition issues. Among the specific activities provided for under this agreement are the sharing of information, the disseminating information on meetings and educational programs of mutual interest, and periodic discussions between agencies to coordinate efforts in areas of mutual concern or to plan for new and/or improved procedures and programs for implementation.

9. Food Labeling Review

Also during 1989, preparations were made for a major review of the Agency's food labeling policies. This initiative, which will be the most comprehensive review of food labeling in the past two decades, will cover a wide spectrum of food labeling issues, including nutrition labeling, labeling format, ingredient labeling, descriptions of food, and health messages on food labels.

This initiative provides for extensive public participation in the food label review process. A Federal Register Notice will solicit public comment on the specific issues which need to be addressed. The Agency is holding a series of public hearings around the country in order to obtain first hand information regarding attitudes, opinions, needs and expectations concerning reform in food labeling policies from industry, consumers, health professionals, as well as state and local government officials. Moreover, smaller consumer exchange meetings will beheld in other areas where hearings are not convened. Public hearings have been held at Chicago on October 16, 1989, San Antonio on November 1, 1989, Seattle on December 7, 1989 and Atlanta on December 13, 1989.

HUMAN DRUGS

STATUS OF PROGRAM

The Human Drugs program is responsible for assuring that all drug products used for the prevention, diagnosis, and treatment of disease in the U.S. are safe and effective, properly labeled and that information on proper use is available to all users.

Current Activities. To accomplish these responsibilities, FDA:

1. Evaluates the safety and effectiveness of drugs before permitting marketing, and monitors preclinical and clinical testing of new drugs.
2. Monitors the short and long-term effects of marketed drugs, including their utilization, to discover potential safety problems and establish a scientific basis for regulatory actions.
3. Develops and publishes monographs for monitoring over-the-counter drug products on the market.
4. Monitors the quality of marketed products through surveillance and compliance actions; conducts inspections of manufacturing establishments to ensure compliance with established regulations and good manufacturing practices and removes those products from the marketplace not meeting standards, including fraudulent health products.
5. Conducts research to establish product standards and develops analytical methodology and improved test methods.
6. Disseminates drug information to the medical community and the public, including development and implementation of labeling standards.
7. Monitors product advertisements and promotional labeling and enforces requirements for accurate and balanced representations.

Selected Examples of Recent Progress:

1. Acquired Immune Deficiency Syndrome (AIDS)

The conquest of AIDS has been identified as the nation's number one health priority. FDA has a key role in the Public Health Service's initiatives being pursued to meet the challenge of the AIDS epidemic. FDA oversees the approval of safe and effective drugs used in the prevention and treatment of HIV infection, AIDS and AIDS-related opportunistic infections. Furthermore, FDA research scientists have joined with others througnout the biomedical scientific community in a massive research effort to identify therapeutic modalities to treat HIV and HIV-related diseases. Particularly important have been FDA staff efforts to expedite the drug development approval process and to increase early access to promising new therapies for this disease.

Under the overall guidance of the PHS Executive Task Force, interagency committees were established to deal with AIDS initiatives in eight major areas: therapeutics, vaccines, information and education, epidemiology, intravenous drug abuse, patient care needs, neuroscience and behavior, and blood safety. Coordination of the screening and clinical testing of products identified as potentially useful for the treatment of AIDS has been achieved through close interaction between these groups at the working staff level. This coalition of talent and interagency dialogue will help to ensure early availability of new AIDS therapies to patients as promptly as is scientifically and ethically appropriate. It will also provide an efficient mechanism for the sharing of information with non-AIDS specialists within the medical community and with the general public.

FDA's efforts in this process include: 1) facilitating development of promising new therapies; 2) reviewing data submitted in support of applications for investigations of experimental products, or for applications requesting permission to market such products; and 3) conducting research targeted toward resolution of specific problems that might hinder an experimental product's development and approval. Products included in this process are therapeutic agents directed against the AIDS virus itself and the opportunistic infections associated with the disease, products that might repair the immunologic deficits seen in the disease, and products for immunizing against the AIDS virus or serving as a barrier to the transmission of the virus.

FDA is taking a number of specific actions to assure that the highest priority is given to applications for products that will treat, cure, or prevent AIDS and AIDS-related diseases; and to give high priority to AIDS research. These actions will include the following specific initiatives.

Speeding the Availability of New Therapies. Expediting the availability of new products for HIV and HIV-related diseases has been a major priority of FDA over the past several years. FDA has assigned all such potential therapies a 1-AA designation--the highest priority in the drug review process--and will take all measures necessary to assure prompt administrative processing and scientific review of HIV-related submissions.

Expanded activities by industry, academia, and FDA to develop treatments for AIDS have significantly increased the number of product applications submitted for FDA evaluation with every expectation of continued growth. In addition to product application reviews, FDA must inspect manufacturing establishments, and develop standards and methodologies for validation and testing strategies.

FDA will continue to expedite the review and evaluation of investigational new drug applications (INDs) and new drug applications (NDAs) for all promising AIDS-related therapeutics and facilitate therapeutics development and availability. This commitment on the part of FDA includes increased communication with sponsors regarding preclinical studies and clinical trial design and conduct, active monitoring of the progress of clinical trials, and increased reliance on postmarketing surveillance and phase 4 (post-marketing) clinical trials. FDA will expand upon the current practice of early and continued consultation between FDA and therapeutics sponsors to provide guidance on efficient and effective drug development. The Agency has formalized this process by publishing interim regulatory procedures on October 21, 1988 designed to further speed the availability of new therapies to desperately ill patients, including those with AIDS, while preserving appropriate guarantees for safety and effectiveness.

Research Efforts. The principal focus of FDA's research efforts has been in the study of the pharmacology of anti-AIDS drugs, especially nucleoside analogs. As more drugs are entered into testing (and new INDs are filed), priorities change quickly. The overall intention is to provide a laboratory which has the capability and flexibility of reacting to new development while maintaining a set of core projects of continuing interest.

FDA will continue to undertake focused regulatory research on critical rate-limiting aspects of the preclinical, chemical manufacturing, and clinical phases of drug development and evaluation when FDA review identifies the need for important additional information that could facilitate the clinical development of the drug.

An additional area of interest is the delivery of drugs in aerosolized form. Aerosolized pentamidine was approved in 1989 for prophylaxis of Pneumocystis carinii pneumonia, and it is anticipated that there will be other proposals for delivery of drugs as aerosols and that the pharmacokinetics of aerosol delivery will become a part of FDA's research efforts, especially for the treatment of patients who are co-infected with HIV and Pneumocystis carinii pneumonia. There is very limited information available regarding the most appropriate means to calculate and regulate absorbed doses for the patient, and FDA will also focus on this as a research effort.

Prevention/Education. FDA plays a role in educating the public and health professionals on preventing the transmission of HIV through the reduction of high risk behaviors and maintenance of low risk behaviors. FDA will develop a program on health fraud and AIDS to minimize the amount of misinformation, quackery and health fraud associated with products to prevent or treat AIDS.

2. Improving the new drug review process

FDA has a direct and major impact upon the quality and cost of health care as a consequence of the roles it plays in the regulation of research on new drugs and in the approval of new drug products for marketing. To the extent that it is successful in implementing these roles in an effective and timely manner the American public receives important benefits. Achieving improvements in the new drug regulation process has been, and remains a top priority for the Agency and, accordingly, is a major theme of the FDA Action Plan Phase III. As evidence of the success of this commitment, FDA approved 13 new chemical entities in 1989, 79 New Drug Applications (NDAs), and received and initiated review of 30 Computer Assisted New Drug Applications (CANDAs).

Reviewer Recruitment and Fellowship Programs. Other efforts to improve the drug evaluation process include working intensively with the Institute of Medicine, the National Institutes of Health, the American Medical Association, and the Pharmaceutical Manufacturers Association to recruit, through fellowship programs, and other innovative mechanisms, applicants with the scientific expertise needed to conduct high quality drug reviews. FDA has also, through three separate task forces, studied ways of increasing the effectiveness of the FDA recruitment program for medical officer reviewers; explored the development of a Distinguished Fellow Program and developed a structured multi-year university-affiliated fellowship program designed to augment the medical officer review staff.

FDA's fellowship programs are offered as a means to provide regulatory science training to the participants, and to promote recruitment of qualified personnel to FDA upon completion of the program. In 1989 FDA's fellowship program was increased to six.

FDA also established a Center for Drug Evaluation and Research Staff College to, among other activities, develop and teach courses in pharmacokinetics, statistics, clinical trial design, and pharmacoepidemiology for new and present review scientists. Additionally, the staff college is utilized to develop and manage a variety of fellowship programs.

3. New IND Regulations and Policies

Under FDA's treatment IND regulations, which became effective in June 1987, drug developers may receive approval to provide promising experimental therapies to patients with immediately life-threatening or certain serious conditions before complete data on the drug's efficacy are available to enable approval for full commercial distribution. Since implementation of the treatment IND regulations, 17 requests (15 drugs and two biologics) have been granted for treatment IND status under these regulations. Those permitted to proceed in 1989 were as follows:

- Pentamidine Isethionate Aerosolized, for prevention of Pneumocystis carinii pneumonia in AIDS patients;
- Levamisole hydrochloride, for use (with 5-fluorouracil) as an adjuvant treatment for Dukes C adenocarcinoma of the colon;
- Erythropoietin (EPO), for treatment of zidovudine (AZT) related anemia in HIV positive patients;
- Exosurf (synthetic pulmonary surfactant), for preterm infants at risk for or demonstrating respiratory distress syndrome;
- Dideoxyinosine (ddi), for treatment of patients with AIDS or AIDS-related complex who are intolerant to zidovudine;
- Survanta (bovine pulmonary surfactant), for prevention and treatment of respiratory distress syndrome in premature infants;
- Retrovir (zidovudine), for treatment of pediatric patients with HIV disease.

- Ceredase (beta-glucocerebrosidase), for chronic enzyme replacement therapy in the management of patients with Gaucher's disease (Type I); and

- Fludarabine, for chronic lymphocytic leukemia.

All treatment INDs are considered a bridge to NDA approval. The first treatment IND was allowed to proceed on December 24, 1987. Of the 17 treatment INDs allowed to proceed, four now have approved new drug applications (NDAs); one has a pending NDA; and reviewing divisions have met with firms to discuss the submission and format of NDAs for six other treatment INDs.

Additional new IND regulations (also known as Subpart E) were published in the October 21, 1988 **FEDERAL REGISTER** that will permit drug companies to market promising drugs for serious and life-threatening illnesses without having to conduct Phase 3 clinical trials if adequate data are generated in Phase 2 trials to demonstrate that the drug is safe and effective. FDA's primary goal under this regulation is to move promising therapies through laboratory, animal and human research as quickly as possible to make these therapies available earlier to patients.

These regulations encourage researchers to accelerate and condense their studies and assure that FDA will realistically balance the risks and benefits of promising drugs in light of the severity of these conditions. FDA will work with the sponsor early in the process to reach agreement on the most time-efficient animal and human studies necessary to determine safety and efficacy. FDA and the drug sponsor will meet at the end of Phase 1 to discuss the results of the Phase 1 studies and to reach agreement on the design of Phase 2 trials with the objective of acquiring definitive efficacy data on which approval may be based. By this cooperation, it is hoped that adequate evidence of safety and efficacy will be generated in Phase 2 controlled trials and the need for additional Phase 3 trials can be eliminated. Elimination of this phase is expected to reduce the time required for human testing of drugs from one-third to one-half the usual time.

During 1989, FDA took steps to expedite this process by taking the following actions: provided for early consultation with drug sponsors (Phase 1 and 2) by establishing policy and procedures to be followed via policy memoranda to each of its reviewing divisions; identified candidate drugs for the Subpart E program, a program which began on January 27, 1989 and was completed in March 1989; and modified its Management Information System for tracking Subpart E designees, completing this activity in October 1989.

FDA's implementation of the Treatment IND regulations and the interim regulatory procedures for expediting development and availability of drugs for life-threatening and severely debilitating diseases has been extremely successful for therapies intended to treat AIDS and AIDS-related illnesses. Of the 17 treatment-use INDs approved since the regulation became effective on June 22, 1987, six were for AIDS or AIDS-related conditions, and two of these drugs, aerosolized pentamidine and ganciclovir, were subsequently approved for marketing based on limited but adequate data in accordance with the October 21, 1988 interim rule.

At the present time, FDA is working with its sister Public Health Service agencies and the National AIDS Program Office (NAPO) to develop procedures to increase access to promising investigational drugs for AIDS and HIV-related illnesses under a "parallel track" mechanism before there is any definitive evidence of either safety or efficacy of the drug. Under the proposed program, selected investigational drugs would be made available under the parallel track at the same time as the major controlled clinical trials are conducted. Currently, the controlled clinical trials for ddi (ddi versus zidovudine as the control drug) are being carried out simultaneously with distribution of the drug under a treatment IND for patients who cannot enter the controlled clinical trial because of serious toxicity reactions to the control drug. Under a prototype of the proposed parallel track program, patients who are ineligible for both the controlled trial because that patient has shown drug resistance to the control drug and the treatment IND because that patient has not had serious toxicity reactions to zidovudine may receive ddi under an open, nonconcurrently controlled protocol.

4. Generic Drugs

In 1989, a number of abuses were disclosed in the area of the generic drugs program including submission of false data, submission of false samples, illegal gratuities and favoritism. To prevent the occurrence of such activities in the future, FDA instituted many changes in this program. At the same time, the changes will provide for prompt review of generic drug applications so that consumers and government providers of health care can be assured of the quality of generic drug prescriptions.

FDA began an intensive expansion of inspectional efforts to assure the safety of generic drugs now on the market, as well as long range efforts to enhance both the applications review process and field surveillance and inspections of generic drug manufacturers.

FDA created an Office of Generic Drugs to manage the generic drug review program. This office will include an internal quality control staff to assure that generic drug applications are reviewed quickly and fairly. An Ombudsman was also created in the Office of the Commissioner to serve as a mediation point in cases of disputes between generic drug manufacturers and FDA reviewers in those instances where FDA's normal appeal process has been exhausted.

FDA has increased its efforts in application review and related activities. These increases are designed to allow for a more thorough review of new applications without increasing the review time, and for staffing the newly created Office of Generic Drugs. FDA's efforts to strengthen this process will also take into account the audit of generic drug review and workflow procedures, and will contain input from the audit of these procedures by HHS's Office of the Inspector General. In addition to the Ombudsman created in the Office of the Commissioner, the Office of Generic Drugs will have its own Ombudsman to handle complaints and comments from consumers and industry.

In addition, the agency will increase applied research activities related to generic drugs, especially bioequivalence. In-house research will be supplemented by an extramural contract for clinical bioequivalence studies of drugs.

Two major activities are planned in 1990 to assure the safety of generic drug products on the market and to restore confidence. Surveillance inspections will be conducted for many of the manufacturers of the 2,000 generic drugs approved since passage of the 1984 law. FDA investigators will examine product samples, inspect manufacturing records, and conduct other reviews to assure that the drug is formulated and manufactured as stated in the Abbreviated New Drug Application (ANDA). FDA will look at company records to determine if the manufacturer is receiving its active ingredient from an approved supplier. In addition,the agency plans to substantially expand its laboratory testing of generic drug products, and increase its bioequivalency studies of generic drugs.

Beginning in 1990, FDA will add quality assurance inspections related to all approved ANDAs to the biennial inspection requirements to determine if the firm is following its ANDA submission. FDA will increase the number of tests conducted to determine the identity of all active and inactive ingredients, and will conduct tests to detect product substitution, and other potential fraudulent activities. Finally, the agency will institute regular audits of bioequivalence data generated by independent testing companies used by the drug firms. This will determine if the product submitted for testing by an independent laboratory is the identical product manufactured by the applicant, as well as determine if the method actually stated in the application has been used by the laboratory.

5. Strengthening Postmarketing Surveillance Activities

FDA has continued to strengthen postmarketing surveillance activities to protect consumers against new and unforeseen risks with marketed products. Activities in this area included implementing industry-wide voluntary submission of computer reports; initiating the development of a computer procedure for producing completed adverse reactions reporting forms (FD 1639s) from FDA's computer file; increasing the awareness of health adverse drug reactions; conducting pilot projects to increase reporting; linking with international organizations to broaden the base of experience reporting; and expanding epidemiologic research. A total of 67,442 adverse drug and biologics reactions reports were evaluated in 1989.

Pilot tests with health departments in four different states initiated in 1985 to promote awareness and understanding of the adverse drug reactions reporting system and to promote interventions to increase the quantity and improve the quality of reports received directly from health care providers are continuing. The pilot projects have been a success and the knowledge gained, the educational interventions developed and the increased flow of reports through the contracts have shown that the maintenance of reporting centers at the state level is a viable effective method to expand the number of direct reports received annually by FDA. Subsequently, FDA plans to award contracts for the maintenance of three to five sentinel adverse drug reactions reporting areas as well as expand the program into hospitals.

FDA expanded its epidemiological data bases by awarding three contracts for tracking the impact of new drugs on acquired immunodeficiency syndrome (AIDS) therapy.

6. Over-the-Counter (OTC) Monograph Development

Through rulemaking procedures, the Agency continues to establish standards for therapeutic categories of OTC drugs by publishing final monographs or regulations in the FEDERAL REGISTER. To date, twenty-six rules have been published.

Eight important over-the-counter documents were published in the FEDERAL REGISTER in 1989: final monographs for nighttime sleep-aid drug products and expectorant drug products; final rules for hair grower and hair loss prevention drug products and aphrodisiac drug products; tentative final monographs for internal analgesic, antipyretic, and antirheumatic drug products, pediculicide drug products, astringent drug products and menstrual drug products. FDA also published a final rule amending its tamper resistant packaging regulation to require only one instead of two tamper-resistant packaging features for hard gelatin capsules sealed by tamper resistant technology such as gelatin banding.

In addition, FDA published a policy statement announcing that cough-cold combination drug products containing promethazine hydrochloride may not be marketed OTC at this time to allow the agency to consider thoroughly additional data and information submitted on the safety of marketing of these drug products.

7. Drug Enforcement Actions in 1989

Selected major enforcement actions for the year include:

> In February 1989, a sponsor investigator who had two investigational new drugs (INDs) to conduct studies with pentosanpolysulfate Na (Elmiron) on patients with interstitial cystitis and cancer, agreed to be ineligible to receive investigational drugs and to withdraw the two INDs. The investigator was found not to have tested the IND products but rather to have treated patients with additional products, including pharmacologically dangerous substances, without warning and adequate medical follow-up.
>
> In April 1989, as a result of a two year joint investigation by FDA, the U.S. Postal Inspection Service, and the Federal Bureau of Investigations, two of the largest known manufacturers and distributors of counterfeit anabolic steroid products in the U.S. entered guilty pleas before a federal district judge. The two defendants trafficked in both real and counterfeit anabolic steroids, and operated two clandestine manufacturing laboratories as well as a number of storage facilities in the South Miami area. They were also the largest suppliers of steroids in the Virginia, Maryland, and Washington, D.C. area.

8. Anti-Drug Abuse Act of 1988

Evidence of escalating illegal use of anabolic steroids is of continuing concern to FDA. Although voluntary compliance efforts between FDA and anabolic steroid manufacturers and distributors have significantly reduced the diversion of legitimate anabolic steroids as a source of black market supplies, clandestine manufacturing and illegal imports continue as the predominant sources of illicit steroids. Distribution channels and activities closely resemble those for other illicit drugs such as cocaine.

Section 2403 of the Anti-Drug Abuse Act of 1988 increased the penalties for illegal distribution of anabolic steroids under the Federal Food, Drug, and Cosmetic Act. The new legislation also applied the forfeiture provisions of the Controlled Substances Act for these felony violations. A number of Federal, state, and local authorities are now pursuing anabolic steroid cases and applying the new forfeiture provisions as appropriate. FDA is assisting the Department of Justice in coordinating anabolic steroid investigations and litigations, and an increasing number of indictments are pending. Comprehensive investigations into the illegal use and distribution of steroids will be continued, as will public education efforts for health professionals, consumers, and users. In addition, FDA will continue its traditional role of consulting with DEA on issues such as the proper medical uses, and the level of drugs needed for such uses of controlled substances.

9. Health Fraud

A significant proportion of the total number of health fraud actions approved by FDA continue to be regulatory actions against products fraudulently promoted for the treatment or prevention of the spread of the acquired immunodeficiency syndrome (AIDS) virus, or touted as enhancing the human immune system. Of the 57 regulatory actions approved by FDA in 1989, 20 involved one or more products promoted with AIDS treatment or immune system enhancement claims, or both. The actions included two injunctions, two seizures, and 16 regulatory letters. In 1988, 46 of the 148 regulatory actions approved by FDA involved products with similar bogus claims.

ORPHAN PRODUCTS DEVELOPMENT

The Food and Drug Administration has continued to carry out a program to encourage the development of drugs, biologicals, medical devices, and medical foods for rare diseases or conditions. The Agency met with 25 potential sponsors of orphan drugs in 1989. The sponsors were provided with information on development of these drugs and guidance on applying for "designation" as an orphan drug under the Federal Food, Drug, and Cosmetic Act. Additionally, two sponsors requested and received formal "protocol assistance" whereby FDA provided the sponsors with guidance in designing and conducting human studies on drugs for rare diseases or conditions. It is anticipated that such assistance will be continued at this level in 1990 and 1991.

During 1989, the FDA completed scientific reviews on 67 new sponsor requests for designation of drugs as orphan drugs in addition to 46 applications submitted prior to 1989 and amended in response to FDA letters. As part of the review, the sponsor is required to submit data adequately demonstrating the use of the drug for diseases or conditions affecting less than 200,000 people in the U.S. Based on these reviews, 75 drugs received designation as orphan drugs during the year. A total of 332 designations have been made since the enactment of the Orphan Drug Act. It is estimated that FDA will review 135 sponsor requests for orphan drug designation in 1991.

Under the FDA Orphan Products Grant Program $2,337,005 was awarded for 21 new studies in 1989. These studies were designed to provide information on human safety and effectiveness of 20 drugs and one medical device for diseases or conditions such as hemodialysis-associated porphyria, precocious puberty, ulcerative colitis, Wilson's disease, urea cycle enzymopathies, ascites, gonadal failure, lead poisoning, autism, severe spasticity, sickle cell anemia, neuroblastomas, graft-vs-host disease, and homocystinuria. Study of an AIDS-related treatment for M. Avium Complex was also funded. Additionally, $3,062,995 was expended during the year for continuation of studies begun in prior years.

The following designated orphan drugs were approved for marketing in fiscal year 1989.

> Eldepryl (seligiline HCl) - For use as an adjunct in the management of parkinsonian patients being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy.
>
> NebuPent (pentamidine isethionate, inhalation) - For the prevention of Pneumocysitis carinii pneumonia (PCP) in patients at high risk of developing this disease.
>
> Cytovene (ganciclovir sodium) - For use in the treatment of cytomegalovirus (CMV) retinitis in immunocompromised individuals, including patients with acquired immunodeficiency syndrome (AIDS).
>
> Epogen (epoetin alfa) - For the treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis.

Rifadin I.V. (rifampin) - For antituberculosis treatment in cases where use of the oral form of the drug is not feasible.

Based on monitoring or progress on presently designated orphan drugs, it is estimated that new orphan product approvals will continue at the rate of five to seven per year for 1990 and 1991.

Management Improvement Systems and ADP Enhancements

FDA has initiated the development of a database to more efficiently identify orphan designation of products for the treatment of AIDS. FDA also initiated the development of a database to enhance the ability to track, identify and retrieve information on orphan designations and orphan grants.

BIOLOGICS

STATUS OF PROGRAM

The Biologics program is responsible for assuring the safety, effectiveness, purity, and potency of biological products and for assuring the safety of blood and blood products.

Current Activities. To accomplish these responsibilities, FDA:

1. Administers an Acquired Immune Deficiency Syndrome (AIDS) program, including research on AIDS diagnostic tests, therapeutic products, and vaccines and maintains liaison with the PHS AIDS Coordination Staff.
2. Evaluates the safety and effectiveness of biological products before marketing and monitors the preclinical and clinical testing of new biological products.
3. Issues licenses to manufacturing establishments including plasmapheresis centers, blood banks, vaccine producers, and others; and issues licenses for biological products.
4. Maintains the quality of marketed products through surveillance and compliance actions; conducts inspections of licensed and unlicensed biological manufacturing establishments to assure compliance with established regulations and good manufacturing practices; and removes from the marketplace those products that do not meet established standards.
5. Conducts potency and safety tests of certain licensed biological products before they are released for marketing.
6. Maintains up-to-date knowledge of biotechnological techniques and methodologies to foster the development of new products and provide a sound scientific basis for their regulation.
7. Sponsors and conducts research to establish product standards and develops analytical methodologies and improved test methods.
8. Registers regulated manufacturing and blood banking establishments; maintains listings of all biological products commercially marketed in the U.S.

Selected Examples of Recent Progress:

1. Acquired Immune Deficiency Syndrome (AIDS)

The Biologics program has a vital role in FDA's effort to combat AIDS. This is due to regulatory responsibilities associated with extensive knowledge and expertise in the area of applied biological research related to product review and blood bank regulation. Increased activities by industry, academia, and government to develop diagnostics, treatments, and vaccines for AIDS have significantly increased the number of product applications submitted for FDA evaluation. In addition to product application review and licensing, FDA must license manufacturing establishments, certify manufactured batches, and develop standards, reference sera, and methodologies for validation and testing strategies. To date, FDA has received over 300 INDs representing more than 190 unique products for AIDS or AIDS-related diseases. Of these, over 145 INDs, representing more than 90 unique biological products were received to further develop diagnostics, treatments, and vaccines for AIDS and AIDS-related diseases. Applications for AIDS biologics products undergo the most expeditious premarketing review possible. In most cases, FDA grants permission to begin clinical trials within five days of receiving the IND application.

FDA's applied research activities have played a significant role in the development of vaccines, therapeutic agents, and test kits for possible use in AIDS and AIDS-related conditions by defining parameters that must be met regardless of product or sponsor. FDA continues to enlarge the scope of its AIDS-related activities as new data on the AIDS virus and disease accumulates and clinical trials of new therapies, vaccines, and diagnostic tests expand.

Protection of the Nation's Blood Supply. Although the risk of acquiring human immunodeficiency virus (HIV) by transfusion of blood has almost been eliminated, FDA continued its efforts and activities to further reduce such risk and to ensure the safety of the nation's blood supply. A major initiative FDA instituted in 1988 was to increase inspections of blood banks and plasma centers from once every two years to annual inspections. In 1989, FDA conducted 2,816 inspections, or 100 percent, of all such FDA regulated facilities in the U.S. These inspections revealed slight deviations in procedures from FDA regulations. FDA continued to work with the American Red Cross, under their voluntary agreement, to ensure that unsuitable units of blood and blood products are not released or transfused. FDA continued AIDS-related training for field investigators to ensure that adequate reviews are performed related to donor educational materials and all types of recordkeeping and inventory control. In addition, on June 6, FDA proposed requirements for proficiency testing by laboratories performing FDA-required tests for antibody to HIV.

Development and Evaluation of Blood Tests. FDA continued efforts to develop more effective blood tests for the detection of antibodies to and antigens of HIV. At this time over 55 INDs have been approved for trials. To date, FDA has licensed 11 test kits based on ELISA (enzyme-linked immunosorbant assay), Western Blot assays to detect the presence of HIV antibodies, or tests to detect the presence of HIV antigens. The approval of the Western Blot test kit has helped reinstate some previously excluded blood donors and has safely increased the supply of blood available to patients needing transfusions. In addition, FDA is evaluating several other pending license applications for HIV blood test kits.

In August, FDA approved the first test kit to detect the presence of HIV-1 by directly detecting the proteins, or antigens, of the HIV. In May, FDA licensed a new HIV antibody test kit that is the first to use chemically synthesized peptides to represent portions of the HIV. This greatly reduces the risks posed to laboratory workers involved in manufacturing antibody test kits. FDA also licensed a five-minute latex agglutination test which will be especially useful in third world countries.

Research continued on improved antibody tests with enhanced specificity ot antibody detection, particularly toward facilitating the advancement of a rapid, inexpensive, and easily administered diagnostic test for widespread use. These tests are likely to be used in third world countries but may also be useful in other situations in which standard tests may be unavailable or impractical.

FDA actively considered regulatory strategies for blood collection systems intended for HIV testing; commonly called AIDS home test kits. Concerns about how to regulate these tests stemmed from questions regarding the performance of HIV testing outside of a medical setting and included both questions of psychological impact of test results for the patient as well as accuracy of the tests. As a result the agency proceeded cautiously in its approach to these products. After consulting with a series of advisory committees, FDA issued specific medical guidelines, restricting the kits to professional use only within a comprehensive health care environment.

Review and Evaluation. The agency's highest priority has been placed on producing the most expeditious, effective, and efficient premarketing evaluation of products proposed for use in the treatment, diagnosis, and prevention of AIDS and AIDS-related diseases. In this context, FDA announced in October, 1988, the immediate implementation of a plan to help reduce the time required for human testing of these products. Under this plan, FDA will work with manufacturers/researchers more extensively to better focus their efforts early in product development to, when possible, eliminate the last of the three traditional phases of human drug/biologic research.

Since 1985, the number of IND submissions related to AIDS has increased over 450 percent from a cumulative total of 60 in 1984 to an estimated cumulative total of 331 in 1989. To date, seven NDAs/PLAs intended for use against AIDS and AIDS-related diseases have been approved or licensed for marketing. Zidovudine (AZT) was approved in 1987 as an anti-AIDS treatment. Pentamidine (injectable use only) was approved as a treatment for pneumocystis carinii pneumonia (a common opportunistic infection in AIDS patients). Two Alpha-Interferon products were licensed as the first treatment for Kaposi's Sarcoma, a systemic cancer that affects about 10 percent of all AIDS patients. Aerosol Pentamidine and Ganciclovir were approved as the first two products to treat or prevent opportunistic infections. Most recently, Zidovudine syrup was approved as the second dosage form. Six treatment INDs have been approved for promising investigational AIDS therapies. The active treatment INDs include:

- Trimetrexate - To treat Pneumocystis carinii pneumonia;
- Erythropoietin - A recombinant protein product used to treat severe anemia associated with AIDS or the use of AZT;
- Dideoxyinosine (DDI) - A drug product intended to treat HIV infection and AIDS; and
- Zidovudine syrup - In the appropriate dose and formulation to treat children with AIDS and advanced AIDS-related diseases.

AIDS Vaccine Development. Because of the nature of the AIDS virus, scientists predict vaccines against it will take a number of years to develop; however, much progress has already been made in the search of such vaccines.

Clinical trials of candidate vaccines are coordinated by the National Institute of Allergy and Infectious Diseases through their vaccine evaluation units. These trials involve a PHS-wide coordinated program in which FDA has been active in expediting product review, testing, release, and evaluation of data. FDA has expanded efforts to develop potency test methods for various types of candidate vaccines in collaboration with manufacturers. Additional reference reagents will be developed and the correlation between potency test methods and human immunogenicity demonstrated to assure comparability of potency of various products. At this time, seven INDs have been approved for trials of two AIDS vaccines, and several other such applications are in the pre-IND phase.

2. Biotechnology

Biotechnology holds increasing promise of new biological products for the treatment, diagnosis, and prevention of many diseases. Over the past four years the number of investigational submissions received for new biotechnology-derived biological products has increased from 56 in 1984 to 156 in 1988, an increase of over 175 percent. Products of importance produced by the new biotechnology techniques include interferons, interleukins, growth factors, enzymes, lumphokines, monoclonal antibodies, reproductive hormones, antihemophilic factor, tissue plasminogen activator, and vaccines against viral and bacterial diseases.

FDA recently approved a gentically engineered treatment for the severe anemia suffered by patients with chronic kidney failure. The product, called epoetin, is a copy of the erythropoietin protein that normal kidneys make to trigger red blood cell production.

Previously the most common way of treating severe anemia was with blood transfusion. Patients who receive repeated transfusions may develop antibodies which may make it more difficult to identify or match a donor for kidney transplantation or for additional transfusions. Also, repeated transfusions over many years may result in storage of too much iron, with potentially adverse health effects. The new treatment should greatly reduce kidney patients' need for blood transfusions.

In its continuing concern for the expeditious transfer of the advances of biotechnology from the laboratory to the marketplace, FDA has taken the following actions: (1) staffing the Division of Cytokine Biology, a division that was created in response to the tremendous growth in recombinant derived biological products; (2) expanded existing research programs in the areas of cytokine biology, growth factors, organ biology, developmental biology, and blood products to enhance review activities; (3) developed a "user-friendly" assistance program to assist manufacturers with scientific regulatory aspects of product development, manufacturing and marketing; and (4) enhanced efforts to develop "points to consider" documents and guidelines in the biologics area to monitor and educate manufacturers on product issues.

3. Management Improvement Systems and ADP Enhancements

The agency has continued to automate various aspects of biological product evaluation and research. The goal of accessibility of microcomputer technology to all professional, technical and support staff has been met. Installation of the appropriate equipment has improved the ability of employees to rapidly process IND and license applications, regulatory correspondence and requests for release of lots of approved vaccines and blood products. Installation of state-of-the-art scientific workstations for molecular modeling, cell biology, DNA sequence analysis, and other intramural research programs allows development of methodologies concurrently with industry for testing the safety and efficacy of potentially licensable biological products.

AIDS On-Line Information. In July 1989, FDA put into operation an on-line computerized database listing through which AIDS patients and their physicians can get up-to-date information on clinical trials of AIDS drugs and vaccines — whether federally or privately sponsored — and the general criteria for participating in these trials.

The AIDS Clinical Trial Information Service (ACTIS) — mandated by the Health Omnibus Programs Extension Act passed in November 1988 — was designed to provide greater access to information about trials underway to test the efficacy of proposed treatments for AIDS and related conditions. This database contains information on every experimental AIDS and AIDS-related treatment undergoing clinical testing for efficacy in FDA approved trials. Since its inception in mid-1989, ACTIS has received over 10,000 phone calls representing all fifty states. Over 70 percent of these phone requests are from either patients or health care professionals.

Document Control Room. The submission of increasing numbers of Investigational New Drug Applications (INDs) and Product License Applications (PLAs) for biological products has made modernization of the document control system imperative. A contract was awarded for development and operation of a document control system. An integrated information processing strategy was developed which set priorities for manual and automated document control and created the necessary processes and procedures for document handling. Implementation began with reformatting of the entire collection of INDs and PLAs to improve access to data and consolidate document storage space. A computerized tracking system was developed and is operational for the INDs. Procedures are now being developed for a tracking system for PLAs.

Electronic Product License Applications. FDA is participating in a pilot trial of an electronic Product License Application (PLA) with a firm that is collaborating in this effort by submitting both hard copy and computer disk versions of the PLA. Having the PLA available on disks will allow for a more thorough analysis of the data, provide screening for specific topics in the PLA, and make reports easier to write, in addition to reducing the cumbersome volumes of paper in the traditional PLA submission. Communication between reviewers and key firm personnel will be expedited through electronic mail.

4. Expanded Regulatory Training

Advanced regulatory training on the technical aspects of blood banking; inspectional and investigational techniques; and compliance strategies for headquarters and field investigational and compliance personnel was conducted during 1989. Two week-long courses addressed new technologies in use, including computerization and automated plasmapheresis techniques.

Training in laboratory quality assurance was conducted over a three month period at each of 22 district offices. Investigational techniques to challenge laboratory quality assurance procedures were taught in response to increased instances of recalls of blood and blood products. In addition to FDA investigators and compliance officers, HCFA and State representatives who would be doing blood bank inspections for HCFA also attended.

FDA also held two compliance workshops for the American Association of Blood Banks to give an overview of compliance with the CFR and FDA inspectional procedures and to highlight current problems in the blood and blood products industry. These workshops were designed to increase industry understanding of FDA's licensing and regulation of blood banks and to assist institutions in complying with FDA's inspectional requirements.

5. Vaccine Development

In 1989, FDA licensed two vaccines, an improved Haemophilus b Conjugate vaccine and a Hepatitis b vaccine. The new Haemophilus b Conjugate vaccine was licensed for routine immunization of all children at 18 months for prevention of meningitis caused by H. influenzae type b, the leading cause of infant meningitis in the U.S. FDA continued to evaluate Haemophilus b Conjugate vaccines submitted by additional manufacturers. These products pose a regulatory challenge as each vaccine is unique in terms of the particular carrier protein and the chemical methods used to couple the H. influenzae type b polysaccharide to it, as well as the size of the polysaccharide used. No single set of standards can be developed which would apply to the control of every Haemophilus b Conjugate vaccine. FDA and the World Health Organization are actively working on standards for these vaccines.

The Hepatitis B vaccine is effective in protecting infants born to women testing positive for hepatitis B virus (HBV) antigens. Without vaccination, 65 to 90 percent of these infants would become chronic carriers. Introduction of vaccination against hepatitis B is being considered for universal childhood immunization.

FDA has also made substantial progress in analyzing and describing the composition of strains of Respiratory Syncytial Virus, which is the most frequent cause of severe, often fatal, bronchitis in infants below one year of age. Understanding the antigenic composition of different isolates of the virus is essential in devising proper strategies for development and usage of an effective vaccine.

ANIMAL DRUGS AND FEEDS

STATUS OF PROGRAM

Current Activities. The Animal Drugs and Feeds program is designed to ensure that veterinary drugs are safe and effective, that animal feeds are not adulterated, and that animal drugs or feeds do not constitute a human health hazard because of residues which remain in meat, milk and eggs. To carry out this mission, FDA:

1. Evaluates Notices of Claimed Investigational Exemption for a New Animal Drug (INAD) and New Animal Drug Applications (NADA) to ensure that drugs will be safe and effective for animals and that no harmful drug residues will occur in food derived from animals.
2. Monitors the veterinary drug production industry by review of Drug Experience Reports required for approved animal drugs and inspecting plant facilities and collecting and testing drug samples, and taking regulatory actions when indicated.
3. Monitors feed and feed ingredients, reviews and approves medicated feed applications, inspects feed mills, and conducts industry information programs to ensure that animal feeds are not adulterated. Takes regulatory action when indicated.
4. Conducts follow-up investigations of USDA reports of drugs, pesticides or industrial chemicals in edible animal tissue, and continues joint efforts with USDA to determine and reduce the incidence of animal drug residues in meat. Takes regulatory action when indicated.
5. Develops rapid screening methodologies that can be used by the U.S. Department of Agriculture (USDA) for surveillance of drug residues and by FDA for supporting regulatory activities. Assists the states by assuring that adequate methods are available for measuring drugs in animal feeds.
6. Conducts regulatory research related to tissue residues and toxic compounds in animal feed, and studies the toxicity, tissue residues and pharmacokinetics of veterinary drugs in food animals, including minor species.
7. Prepares for new technologies and emerging industries such as aquaculture, biotechnology and the impact of automation.

Selected Examples of Recent Progress:

1. Review of New Product Applications

During Fiscal 1989, the Office of New Animal Drug Evaluation acted on 5,713 submissions for new animal drug applications (NADAs) and investigational new animal applications (INADs). Of these 167 were on original new drug applications, and 3,496 were on supplements to previously submitted applications. Approximately 91 percent of the 5,713 decisions were made within the statutory limit of 180 days for NADAs and the internally established time frame of 90 days for INADs

In Fiscal 1989, the Agency approved 21 NADAs. These approvals included albendazole oral suspension, a new chemical entity, for use as an anthelmintic in cattle; maduramicin ammonium, a new chemical entity, for use as a coccidiostat in chickens; carnidazole for use as an aid in the treatment of ulcerative enteritis in quail; zeranol for use as a growth promotant in cattle; ivermectin chewable cube for use as an aid in prevention of heartworm in dogs; and isoflurane for use as an anesthetic in dogs.

2. Monitoring Illegal Use of Animal Drugs

The Agency has made substantial progress in its efforts to ensure that potentially harmful drug residues do not remain in foods. FDA-approved veterinary drugs--some 3,700 (including distributors)--account for 90 percent of all marketed drugs used in food animals. The remaining unapproved products which FDA has not sought to remove from the market include vitamins, minerals and other substances, such as animal liniments, that have no known risk to humans, as well as some medications and other products for non-food animals. During 1986, the Agency developed an automated data system to improve its knowledge of animal drugs in the marketplace. At this time, there are over 14,000 drug products in the automated inventory. The inventory is being used to alert the Agency when unapproved animal drugs may present a potential health hazard.

FDA also believes a mechanism, similar to that used for human drugs, is needed to control the illegal distribution of veterinary prescription drugs among animal producers. The key to effectiveness of such a system is the establishment of a full partnership with the states, including the state licensing of wholesale distributors and pharmacists. With this in mind, the Association of Food and Drug Officials, in conjunction with other state regulatory officials, and with FDA's assistance, approved a model veterinary drug code which should provide a basis for uniform state laws and regulations for veterinary drug distribution. FDA has a contract with the state of California to conduct investigations into the illegal sale and distribution of prescription animal drugs. Evaluation of data from previous contracts with Colorado and Arkansas Departments of Health indicates that such contracts can be very successful.

3. Tissue Residue Monitoring

The tissue residue monitoring program, conducted by USDA for meat, in conjunction with similar programs conducted by FDA (in cooperation with state agencies) for milk, eggs and animal feeds, is the foundation of the government's efforts to ensure that the nations animal-derived food is safe. Effective monitoring depends upon the availability of reliable, efficient analytical methods to detect residues of toxicological concern. In addition to the five states previously involved in follow-up investigations to USDA reports of violations (Pennsylvania, Virginia, West Virginia, Maryland and Delaware), the states of Iowa, Nebraska, Wisconsin, Kentucky, New Jersey, Tennessee, North Carolina, Alabama, Louisiana, Michigan, California, South Carolina, North Dakota, Oklahoma and Texas have joined with FDA in conducting these investigations.

FDA has also joined with USDA to employ the proper measure of voluntary compliance, education, and regulatory enforcement for programs involving sulfamethazine residues in swine. Extensive efforts have also been undertaken with the dairy industry to educate farmers on proper drug use and the need to cease illegal use of sulfamethazine in lactating dairy cows.

FDA is placing increased emphasis on analytical methods development. Emphasis is being placed on the development of new technology to enhance tissue extraction procedures and quantitative analytical techniques. The Agency is particularly concerned with the development of techniques to monitor residues of compounds used illegally in food producing animals and with improving the efficiency of its monitoring program operated in concert with USDA. Of particular importance is the development of methods which can be used to monitor the use of unapproved drugs in meat, milk, eggs and feed.

FDA has nine states under contract to perform follow-up investigations on first time violators. During 1991 it plans to expand this number of states in an effort to reduce residues on a nationwide basis.

4. Implementation of the Generic Animal Drug and Patent Term Restoration Act

Two committees have been formed by FDA to initiate the implementation of the Generic Animal Drug and Patent Term Restoration Act: (1) the Generic Animal Drug Committee and (2) the Bioequivalency Committee. The Generic Animal Drug Committee is responsible for developing regulations and guidelines to implement the Generic Animal Drug and Patent Term Restoration Act. The Bioequivalency Committee is responsible for revising bioequivalency guidelines to comply with the new law.

Four Federal Register documents have been published defining FDA policy for implementing the new law. Draft regulations are currently being reviewed. The proposed implementing regulations are expected to be published by January 1, 1991. The notice of availability of the proposed Bioequivalency Guidelines was published in the Federal Register in June 1989. A number of comments have been received and are being addressed in the revised guidelines.

As required by the Generic Animal Drug and Patent Term Restoration Act, on January 15, 1989, FDA published a listing of all animal drugs approved for safety and effectiveness. The list includes information on patent exclusivity, producer withdrawals, and stability petitions, and is updated monthly. FDA has reviewed several bioequivalency study protocols for abbreviated New Animal Drug Applications. Also, it has written numerous advisory opinions responding to questions on issues related to this Act.

DEVICES AND RADIOLOGICAL PRODUCTS

STATUS OF PROGRAM

The major objective of the Devices and Radiological Products program is to ensure the safety and effectiveness of medical devices and radiological produced and to eliminate unnecessary human exposure to radiation from medical, industrial, and consumer products.

Current Activities. To accomplish these responsibilities, FDA:

1. Reviews and evaluates notices of intent to market products (510(k)s), premarket approval applications (PMAs) and petitions for reclassification. Evaluates investigational device exemption (IDE) requests to ensure that clinical investigations of new devices properly safeguard the rights and safety of human subjects.

2. Conducts research to determine the biological effects of exposure to radiation and performance characteristics of regulated products.

3. Conducts post-market surveillance of regulated products to assess long-term performance; e.g., monitors and evaluates conformance of domestic and foreign establishments with Good Manufacturing Practice requirements; reviews and evaluates reports of deaths, serious injuries, and malfunctions under the medical device reporting regulation (MDR) and initiates follow-up investigations as required; and monitors the device experience network for complaints relating to medical devices; and conducts follow-up investigations as required.

4. Monitors compliance with radiation standards for electronic products such as televisions, microwave ovens, and sunlamps through field tests, review of manufacturers' reports, and investigations (as needed).

5. Performs human factors analysis to determine the impacts of user practices on product performance and develops educational programs for consumers, health professionals, and industry to resolve user problems.

Selected Examples of Recent Progress:

1. Product Review

In 1989, the Agency received a record number of major medical device submissions: PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s. Major submissions received rose from 10,018 in 1988 to 11,195, an increase of 1,177 major submissions or 12 percent. During 1989, 84 original PMAs were submitted and 56 were approved. This represents the second highest number of PMAs ever approved within one fiscal year. The average FDA review time for PMAs continued to fall, from 262 days in 1988 to 247 days in FY89. The number of 510(k)s received rose dramatically to 7,022 for 1989 from 5,536 in 1988. (This was due to an unusually high number of submissions for examination gloves because of our regulatory activities in the AIDS area.) This is the third consecutive year FDA has experienced significant increases in 510(k) submissions. Average 510(k) review time based on both total time and FDA time rose somewhat over last fiscal year, from 78 to 82 days and 64 to 66 days, respectively. Nevertheless, 99 percent of all 510(k) decisions were made within the 90 day statutory review period and there were no 510(k)s that were active and overdue at the end of the fiscal year. After five consecutive years of increases in the number of original IDEs received, the Agency ended FY89 with 241 original IDE submissions, down from 268 in 1988. As expected, the number of decisions was also down, from 260 in 1988 to 245 in 1989. FDA had 16 IDEs pending at the close of 1989 and none of these was overdue. It took an average of 29 days to review the 245 IDEs and, for the first time in the IDE program, all original IDEs were reviewed within the 30 day statutory review period.

Twenty-four new guidance documents for use by industry and FDA reviewers were developed in 1989. These guides, which identify changes in procedures and policies and clarify requirements applicable to the approval program, are intended to promote uniformity and efficiency in program implementation.

2. Significant Medical Device Approvals

A number of PMAs approved in 1989 represent significant advances in medical device technology. The ViraPap TM in vitro diagnostic device, for example, was the first commercially available device to utilize nucleic acid probes for the detection of any of seven specific human papillomavirus types that can infect the cervix. This device is used to aid in the diagnosis of sexually transmitted human papillomavirus infections which are associated with the majority of cervical lesions. The device also may serve as an adjunct to the Pap smear in the identification of women who may be at increased risk of developing cervical intraepithelial neoplasia. Prior to the availability of these DNA probes, none of the seven human papillomavirus types could be identified by routine laboratory tests.

The Belzer UW-CSS Solution is a sterile, nonpyrogenic solution used for the hypothermic flushing and storage (preservation) of human organs in preparation for transplant. Use of this solution increases the time a liver or pancreas is viable between harvest and transplant.

The PACE Urine Screen, an in vitro diagnostic device used to screen for bacteria in urine, represented the first nucleic acid probe for aid in the detection of urinary tract infections. This nucleic acid probe enables the clinical laboratory to speed up the identification of urinary tract infections which, in turn, allows the physician to more rapidly and correctly diagnose the patient's condition.

3. Acquired Immune Deficiency Syndrome (AIDS)

During 1989, FDA continued to focus on activities aimed at educating the public and health professionals about the proper use and reuse of devices to prevent the inadvertent transmission of HIV. For example, FDA produced a three part dental infection control videotape and education package, as well as videotapes for the Bureau of Prisons on measures to control HIV transmission. In the device review and approval area, FDA issued a final regulation rescinding the 510(k) exemption for examination gloves; reviewed more than 1,500 resulting 510(k) submissions for gloves; developed and prioritized a list of devices according to their potential to transmit HIV; provided guidance to manufacturers concerning shelf life labeling for condoms; and performed a review and qualitative analysis of condom labeling and readability. FDA continued its enhanced surveillance of barrier products by sampling, for example, over 2,872 batches of surgical and examination gloves and 246 batches of condoms.

AIDS-related research in 1989 continued to focus on an evaluation of the porosity of condoms and gloves and the barrier capability of natural membrane condoms. A new research project was initiated in 1989 to study the effect of various environmental factors on latex degradation. As a result of FDA's focusing more attention on the role of devices in the nosocomial transmission of HIV, three state contracts were awarded in 1989 to study actual disinfectant practices in hospitals. In the future, FDA will develop materials to disseminate information learned from these studies.

4. Classification

Reclassification of medical devices from class III to a lower, but more appropriate, classification allows products requiring premarket approval to go to market through the less costly and burdensome 510(k) process. In 1989, FDA reclassified the PcCO2 monitor, the ceramic hip prosthesis and the poly(glycolide/L-lactide) surgical suture from class III to class II and published a proposal to reclassify the automated differential cell counter from class III to class II. In addition, FDA received recommendations from its advisory panels to down-classify nonabsorbable poly(ethylene terephthalate), polypropylene, and silk surgical sutures, the porous-coated hip prosthesis, and the suction lipectomy system.

5. Postmarket Surveillance

Postmarketing surveillance (PMS) enhances consumer protection against risks associated with device use, including those which are neither apparent nor foreseen during the premarket notification or premarket review processes. FDA conduct a variety of medical device PMS activities. The major activity is the collection, processing, and evaluation of data received in accordance with the Medical Device Reporting regulation, the Product Problem Reporting system, the Pacemaker Registry, and field investigations. In addition, FDA obtains PMS data as a result of laboratory and statistical analyses of products, from premarket approval applications, and from processing reports and information submitted to the Agency under the Radiation Control for Health and Safety Act.

During 1989, FDA asked manufacturers of extended wear soft contact lenses to change their labeling to indicate a wearing time of one to seven days between removals for cleaning and disinfection. FDA also asked the manufacturers to add new warning statements to the labeling concerning extended wear lenses and, at the same time, informed eyecare professionals of the new data and labeling changes. (Previously, some extended wear lenses were approved for continuous wear from one to 30 days between removals for cleaning and disinfection.) FDA's actions were based primarily on the results of a recent multi-center study of contact lenses and ulcerative keratitis—lesions on the cornea which can be painful and destroy vision. The study results corroborated previous reports derived from FDA data bases and premarket approval applications, and from reports in the scientific literature.

6. Risk Assessment

Problems in the manufacturing process, faulty product design, materials degradation and user errors are examples of the many variables which may adversely affect the performance of a device or radiological product and result in a certain degree of risk associated with its use. Risk assessment activities are important because they enable the Agency to optimize protection of the public health by focusing efforts where they are most needed and they result in data which provides a sound scientific basis for Agency actions involving medical devices and radiological products.

In 1989, for example, FDA scientists initiated testing of intraocular lenses (IOLs) to evaluate the optical quality of lenses being manufactured under Investigational Device Exemptions. (Each year, more than one million of these lenses are implanted after cataract removal to replace the natural lenses of the eye.) A total of 174 lenses were tested for resolution, accuracy of labeled power, and astigmatism. While the lenses from one manufacturer were found to be defective (lenses from this firm are no longer distributed), the test results from the other lenses indicated that the vast majority of IOLs are of excellent optical quality.

In an effort to promote needed research on medical devices outside the government, FDA published, in draft form, a compilation of potential research projects that could fill significant gaps in scientific and technical knowledge about devices. The gaps in knowledge range from basic biochemical, biophysical, or statistical questions to practical methods for gauging device performance, safety, and effectiveness. Although FDA is able to fill many of these gaps through in-house research and by funding research outside the Agency, resource limitations are such that many gaps in knowledge are only partially resolved or are not addressed at all. In these cases, regulatory decisions must sometimes be made in the face of considerable scientific uncertainty; other times, decisions must be delayed until the appropriate data can be developed.

7. User Education

User performance is a key element in the safety and effectiveness of medical devices and radiological products, and in many cases problems with these products cannot be resolved with regulatory actions. Problems may arise if the user (health professional or consumer) is not familiar with the indications for the product and its limitations and potential hazards, or does not have the requisite skills to use it safely. In 1989, for example, FDA initiated development of a program to provide adequate patient information to prospective silicone breast implant patients. This effort was begun after concern was expressed in testimony at a November 1988 meeting of FDA's General and Plastic Surgery Devices Advisory Panel about known and unknown risks associated with these devices. Draft documents for both breast reconstruction and augmentation have been developed and are under review.

8. Assistance to Small Manufacturers

The Medical Device Amendments require FDA to provide special technical and non-financial assistance to small manufacturers of medical devices. The device industry poses a special challenge because of its mix of small "cottage industries" and large corporations. By expanding assistance to these small manufacturers, FDA can improve the level of assurance of safety and effectiveness by improving compliance with the Act and regulations (resulting in cost savings to FDA), and ensure that the benefits of new devices are made available to the public without unnecessary delay.

In 1989, the staff of FDA's Division of Small Manufacturers Assistance increased from 11 to 19 persons. In 1989, the Division sponsored 22 regulatory workshops, collaborated with other organizations on 15 more, and responded to approximately 40,000 telephone requests for assistance. A special focus of the past year was providing information and assistance to foreign manufacturers of examination gloves, whose products are now widely used to help prevent the transmission of HIV.

9. ADP Enhancements to Improve Application Review Processes

In October 1986, FDA entered into a contractual agreement to lease an optical disk storage and retrieval system. The system was acquired to test optical disk technology as a solution to many of the Agency's paperwork management problems. Optical scanning technology provides a valuable management tool, offering the following advantages over existing systems: (1) Efficient document storage and retrieval. The system would allow rapid storage and access of the product applications FDA receives. It is especially attractive to FDA because a single document, optically stored, may be accessed by a variety of users simultaneously in various geographical locations. Once converted to optical image, space required for hard copy can be eliminated; (2) Document tracking savings and maintenance of document integrity. The need for tracking systems to chart the location of applications throughout the various approval points is virtually eliminated by the optical storage of the document, which then becomes instantly available to all potential review offices. At the same time, the integrity of the master document is automatically maintained. (3) Optical scanning provides considerable advantages over existing systems for handling FOI requests by allowing the user to access stored documents, purge information on-line, and then print the edited copy while maintaining the integrity of the master document. (4) Integrated information system. The technology has wide applicability for making current information available to FDA staff on a variety of programs. FDA envisions storage of information from numerous sources--postmarket surveillance data, news clippings, product evaluation applications--being networked into an integrated system capable of providing a complete summary of all the background available on a given product.

In 1989, FDA evaluated commercially available products and determined that for its medical device applications, its needs could best be met by designing its system in-house. Subsequently, five personal computers were purchased for use as image workstations. An optical platter jukebox was purchased and software development was begun. FDA will begin expanding the system in 1990. Equipment to enhance 15 existing personal computers for imaging is already on order, and software developers plan to have the first version of the software completed by early January.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

STATUS OF PROGRAM

The efforts of the NCTR are directed toward developing a better capability to assess risks associated with potentially toxic chemicals, with the following emphasis: determination of the basic biological processes involving chemical toxicants in animal organisms in order to facilitate better extrapolation of toxicological data from laboratory animals to man; development of improved methodologies and test protocols for evaluating the safety of chemical toxicants; and determination of the adverse health effects resulting from long-term, low level exposure to chemical toxicants (food additives, residues of animal drugs, etc.).

Current Activities. To promote the accomplishment of the research goals at NCTR, FDA conducts the following activities:

1. Develops improved systems to study reproductive, developmental, and neurotoxic effects of toxic substances.

2. Develops whole live animal studies and in-tissue culture techniques which can be used to assess carcinogens, and develops systems which can be more directly related to the human.

3. Conducts research to facilitate extrapolation of findings in cellular tissue and animal systems to understanding human disease development and well being.

4. Studies cellular repair mechanisms, DNA damage and repair mechanisms important in the early stages of cancer development, and examines the molecular events which may lead to mutations or disease, and in the case of repair, to maintenance of the normal state.

5. Develops biotechnological approaches to degrade hazardous waste. Research has focused on using simulated environmental microcosms for isolation, enrichment, and engineering of specific bacterial and fungal strains capable of deactivation of toxic environmental substances.

Selected Examples of Recent Progress:

1. Risk Assessment

The Agency is seeking to improve current risk assessment procedures and techniques. Accordingly, NCTR is coordinating collaborative research to: (1) improve understanding of the chemical reactions occurring in the human body in association with a toxic chemical; (2) develop markers in the human body that can be used to demonstrate prior exposure to toxic chemicals; (3) improve the design of scientific testing particularly in areas involving extrapolating from the results of animal studies to the likely effects upon humans; and (4) coordinate toxicological research with other government and private research laboratories to conserve resources and share information.

2. Development of Biochemical and Behavioral Neurotoxicology Markers

Exposure to therapeutic, occupational, and/or environmental chemicals is a cause of concern from a human health standpoint. A major consequence of some chemical exposures is known to be higher mental function deficit (such as a heavy metal exposure, e.g., lead). FDA research programs in non-human primate behavioral toxicology is investigating both acute and chronic effects of various drugs and/or toxicants on complex brain function. Such quantitative assessment is monitored by measuring various behavioral tasks using a "test battery" designed to generate behaviors that are known to depend upon specific brain processes, such as learning, short-term memory and attention, motivation, time-perception, and color and position discrimination. This unique system allows FDA scientists to explore the consequences of maternal exposures to such materials on their offspring, to document milestones for non-human primate behavioral performance during development.

The studies being conducted in non-human primates are also being adapted to measure complex brain function in children. Development of such tests allows quantitative and qualitative analysis of similar tasks for both the non-human primate and children and provides the ability to measure the same endpoints in both animal models and human subjects.

3. Extrapolation

A major health concern is the risk of disease resulting from naturally occurring and man-made chemicals. Current research objectives are to determine the dose at which a chemical is relatively safe for use as a drug, food additive, or cosmetic; or, the level of contamination of food, water, or air, resulting from the use of chemicals, that is relatively safe.

The NCTR has developed a computer program for an actuarial analysis of cancer data from long term animal experiments which is designed to mimic lifelong exposures to chemicals. This program is used extensively to provide estimates of lifetime cancer risk adjusted for unnatural causes of death due to chemical toxicity at high experimental doses. Techniques have also been developed to estimate cancer risks from short-term and intermittent exposures to chemicals and for exposures to complex mixtures of carcinogens.

A biologically-based dose-response procedure has been devised for developmental effects. Initial research has focused on the production of cleft palate due to exposure to toxic substances during gestation. Dose-response modeling has also been introduced to estimate neurotoxic effects.

4. Genetic and Molecular Biomarkers for Species Extrapolation

A major research emphasis at FDA is the development of reliable genetic and molecular biomarkers to assess spontaneous and induced somatic mutations in rodents and primates to determine whether they can serve as relevant surrogates for the human. It is generally accepted that mammalian genotoxic carcinogens induce the carcinogenesis process through somatic mutations. Efforts to develop a single gene and chromosomal mutation assay using rodents, primates, and human lymphocytes as dosimeters of exposure to genotoxic carcinogens (as a means to predict the consequences of in vivo induced DNA damage) are very promising. In addition to quantifying the frequency of mutations as a function of dose, and evaluating the relationship of altered frequency with induction of tumor, studies will analyze the genomic alteration using molecular biology tools to determine the biological relevance of the mutation. This type of analysis is necessary to make meaningful genetic risk extrapolations across species.

5. Biomarkers for Urinary Bladder and Colo-Rectal Cancer

Human exposure to carcinogenic chemicals such as aromatic amines and nitropolycyclic hydrocarbons come from a variety of sources including air, food, water, cigarette smoke, diesel emissions, and specific industrial processes. FDA has examined the metabolic pathways by which these chemicals initiate the carcinogenic process. From experiments in appropriate animal models and their application to clinical and occupational studies in humans, several critical biomarkers have been identified that appear to be predictive of carcinogen exposure or of individual susceptibility to these compounds. For urinary bladder cancer, the acidity of the urine and the frequency of urination have been implicated as the major determining factors that lead to bladder DNA lesions and result in cancer induction. For colo-rectal cancer, a specific enzyme called O-acetyltransferase is important to that process and was first identified at FDA and extensively characterized in the laboratory.

6. The Role that Microorganisms Have in the Degradation and Detoxification of Potentially Hazardous Compounds

FDA research is focusing on the isolation of microorganisms which can either degrade, detoxify, or accumulate toxic chemicals and determine their potential use in the bioremediation of toxic waste sites. Bacteria can degrade and detoxify a wide range of toxic chemicals. The environmental risk assessment and management of potentially hazardous chemicals requires information on their occurrence, toxicity, bioavailability and persistence in the environment. FDA research has developed multi-component environmental microcosms which are useful for determining the rate and pathways for the environmental biodegradation of xenobiotics. The use of these microcosms containing components from ecosystems will enable researchers to predict a range of values for the environmental persistence of toxic chemicals.

FDA's research goals are to isolate microorganisms from hazardous waste sites which have the ability to metabolize and detoxify pollutants; determine the relationship between chemical structure and mineralization rates; determine whether differences in the physical, chemical and microbial characteristics of ecosystems predictably affect the disposition and persistence of chemicals in the environment; and to further develop multi-component microcosms containing sediment and water collected from chemically contaminated sites to determine the rate and extent of degradation of hazardous chemicals.

PROGRAM MANAGEMENT

STATUS OF PROGRAM

This program involves FDA's central program direction and administrative functions. In addition, it also is charged with issues which are agency-wide rather than single program concerns. The Agency will continue to place emphasis on the economic analysis of regulations, improving the exchange of scientific information, strengthening Agency compliance policy, and responding to Congressional and public inquiries. In particular, the Agency will continue its efforts to review and consolidate administrative support functions where possible and economical, and its efforts to make increased use of automation wherever possible to enhance the quality and efficiency of support operations.

Selected Examples of Recent Progress

1. Freedom of Information

The impact of the FOI Act on agency resources has been substantial. The Agency has responded by creating a small central FOI staff, which is the focal point for coordinating responses, as well as by allocating manpower in all major components of FDA, to respond to approximately 40,167 FOI requests a year.

The FOI Act Amendments of 1986, required OMB to issue a uniform schedule of fees for all agencies. Agencies, in turn, were required to issue their own implementing regulations based upon OMB's schedule. The HHS FOI Regulations, which became effective November 13, 1987, provide for new fees and the total collected has increased. FDA collected approximately $658,993 in calendar 1989, compared to $355,000 in 1988, and expended approximately 117 staffyears for FOI requests in calendar year 1989. (All FOI collections are deposited to miscellaneous receipts of the Treasury.)

2. Training Efforts

FDA continues to focus resources on programs and initiatives designed to develop and retain its employees. The agency will focus on the follow major areas:

- Management and Executive Development: FDA will provide training and developmental opportunities to enhance the skills of seasoned managers and to develop the skills of new supervisors and managers.

- Biotechnology: The Agency will continue to devote resources to establishing and supporting training programs in Biotechnology. This vital area is constantly expanding and our programs must expand and grow to help maintain our scientific expertise.

- Expansion of the Staff College Concept Within the Agency: FDA must develop expertise related to the very specialized regulatory functions of a scientific and regulatory agency. Since most universities do not provide curriculums which produce the unique mixture of science and regulation necessary, the staff college concept, which includes design of Agency-specific training courses, contracting with outside specialists to offer Agency-specific developmental opportunities and participation in designing fellowships and cooperative ventures with colleges, universities, and teaching hospitals, will offer FDA another avenue for developing the much needed expertise.

- Other Internal Developmental Efforts: The Agency will continue to provide educational, training and other developmental opportunities for its employees through individual training as well as formal programs such as our Mid-Level Career Development Program, the Short-Term Assignment Training (STAT) Program, the Long-Term Training Program, the Career Opportunities Training Agreement (COTA) programs, the Sabbatical Program, Switch with a Peer (SWAP), and Employee Orientation. The Agency will also continue its efforts to educate employees about their responsibilities in the areas of Conflict of Interest and Ethics.

3. Expanded Regulatory Training and Fellowship Programs to Improve Recruitment

In 1988, FDA instituted research associateship programs with the National Research Council of the National Academy of Sciences and the Oak Ridge Associated Universities in order to rotate postdoctoral scientists throughout FDA laboratories. These programs have two goals. While at FDA, the research fellows will contribute to problem-solving in areas affecting public health. After they leave, the research fellows will constitute a growing cadre of scientists who know FDA, who understand the scientific problems and information gaps FDA faces,and whose careers may improve many FDA-regulated products.

In 1989, Associates continued research at the Center for Devices and Radiological Health aimed at defining the action spectrum for cell-membrane damage and on medical imaging and tissue characterization. A third Associate was selected in 1989 to perform research in the area of fiber optics for laser surgery. In 1990, FDA looks forward to receiving the first Oak Ridge Associate who will conduct research on AIDS-related medical device issues.

FDA's fellowship programs are offered as a means to provide regulatory science training to the participants, and to promote recruitment of qualified personnel to FDA upon completion of the program. In 1989 FDA's fellowship program in the Drugs Program was increased to six. A description of each of these programs is as follows:

Uniformed Services University of the Health Sciences (USUHS)/FDA Clinical Pharmacology

This program offers training in clinical pharmacology and regulatory drug evaluation sciences. Research training is offered in clinical pharmacology including pharmacokinetics, therapeutics, drug metabolism, pharmacoepidemiology, statistics and other relevant areas.

Children's Hospital/Infectious Disease

This program is designed to offer both training in pediatric infectious diseases and experience in FDA drug review. The fellow spends 26 hours per week at FDA evaluating the safety and efficacy of investigational and new antibiotic and other anti-infective drugs, and the remaining time at Children's Hospital participating in infectious disease service duties such as rounds on service patients, consultations from other services and seminars.

PHS Epidemiology Fellowship Program

This is a three-year program designed to attract medical professionals into the field of epidemiology. Program participants spend the first academic year training at an accredited School of Public Health or equivalent academic institution in the U.S., and spending the remaining two years carrying out original investigations, or participating in ongoing studies in the office of an assigned preceptor.

Clinical Staff Fellows

This program is designed to encourage and promote health related research, studies, and investigations, as well as to secure the services of talented scientists for limited periods of time. The participants are given assignments in line with their more moderate level of research experience.

DIA Fellowship in Regulatory Sciences

This program is initiated at Georgetown University in Washington, D.C. in collaboration with FDA, and will provide training in drug regulation and clinical pharmacology. During the first year, the participant will receive a monthly assignment on a regulatory topic. In the second year, they will be given assignments related to the review of Investigational New Drug (INDs) applications and New Drug Applications (NDAs). In the third year, which is optional, the participant will work with a mentor and serve as a primary reviewer on an NDA.

Clinical Pharmacokinetics Fellows

This program provides research and participation in evaluation activities within the Division of Biopharmaceutics. Laboratory activities may involve pharmacokinetic studies in animals, transdermal drug/percutaneous penetration studies, analytical methods development/evaluation and investigation of in vivo/in vitro relationship for targeted drug delivery systems. Pharmacokinetic evaluation experience includes evaluation of IND/NDA pharmacokinetic studies, pharmacokinetic modeling, and statistical evaluation.

In 1990, FDA will develop an additional fellowship program with the National Cancer Institute to provide training in cancer clinical trials, drug law and regulation. The program is also expected to provide compound screening and preclinical toxicology studies, the design of clinical trials of investigational drugs and biological response modifiers; statistical methods relevant to the design and analysis of clinical trials; and principles of drug formulation and drug delivery.

FDA also established a Center for Drug Evaluation and Research Staff College to, among other activities, develop and teach courses in pharmacokinetics, statistics, clinical trial design, and pharmacoepidemiology for new and present review scientists. Additionally, the staff college is utilized to develop and manage a variety of fellowship programs.

ADP SUMMARY

	1989 Actual	1990 Estimated	+/-	1991 Estimated
ADP Obligations by Account/Source				
Salaries and Expenses...	$31,080,000	$39,280,000	+$3,296,000	$42,576,000
Reimbursable............	895,000	1,007,000	+ 35,000	1,042,000
TOTAL................	$31,975,000	$40,286,000	+$3,331,000	$43,618,000
Distribution By Type of Expenditure				
In-House Operations.....	$24,169,000	$30,360,000	+$2,733,000	$33,093,000
Outside Services........	7,806,000	9,927,000	+ 598,000	10,525,000
TOTAL................	$31,975,000	$40,287,000	+$3,331,000	$43,618,000
Distribution By Program				
Foods..................	$4,281,000	$4,793,000	+$1,266,000	$ 6,059,000
Drugs and Biologics.....	8,942,000	11,928,000	- 1,684,000	10,244,000
Veterinary Medicine.....	1,317,000	1,297,000	+ 63,000	1,360,000
Devices and Rad. Products	3,429,000	3,639,000	+ 334,000	3,973,000
National Center for Toxicological Research.	3,132,000	4,375,000	+ 425,000	4,800,000
Program Management......	3,475,000	3,897,000	+ 665,000	4,562,000
Field Activities........	7,399,000	10,358,000	+ 2,262,000	12,620,000
TOTAL................	$31,975,000	$40,286,000	+$3,331,000	$43,618,000

JUSTIFICATION OF INCREASES OR DECREASES

The overall 1991 increase of $3,331,000 reflects general increases of $1,490,000 in personnel and other operating costs for all programs, combined with an estimated $1,841,000 in increased hardware purchases to implement the Field import monitoring data system. Within the program distribution, increased ADP expenditures in some programs will be offset by decreases in others, as major equipment purchases devoted to ADP will occur in some areas in 1990 and in others in 1991.

ADP APPLICATIONS

FDA utilizes ADP applications primarily in two areas: data collection and analysis in its laboratories; and information management of large volumes of data used for inspections, product application review, product monitoring, and other activities. By means of ADP applications FDA is able both to conduct state-of-the-art scientific research and to maximize limited manpower resources in its regulatory efforts. At a time when many scientific discoveries and technological innovations are affecting the products FDA regulates, the application and use of modern automatic data processing capabilities is critical to FDA's effort to base its regulatory decisions on the best science available. Today, scientific laboratories extensively use

ADP equipment to collect, process and analyze experimental data making it possible to obtain results almost immediately thereby saving hundreds of person-hours in many kinds of experiments.

Recent Accomplishments and Improvement Plans

In the area of automated data processing enhancements an FDA Data Standards Manual was recently published and distributed. The goal is to standardize data elements within FDA's ADP systems in order to help link data and systems across organizations and program lines and to improve data sharing throughout the Agency. A committee of Agency representatives reviews and approves data elements for the manual. As new areas are considered and data elements approved, they will be added to the manual. Agency ADP personnel will use the approved data standards to develop new ADP systems and to update existing systems.

A comprehensive software package that provides many office automation capabilities, including electronic mail and calendar management, has been installed for the Office of the Commissioner, the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research and the Center for Veterinary Medicine. Electronic mail can now be exchanged among these components. Special features are being used to allow electronic mail to be exchanged with the Center for Food Safety and Applied Nutrition, the National Center for Toxicological Research, the Office of Regulatory Affairs, and the Denver district office. Use of this system will enhance communications within and among FDA organizations and will help to improve productivity.

Within FDA headquarters information sharing is being enhanced through a communications network consisting of ten separate Ethernet local area networks (LANs). A LAN provides extremely high speed data tied together to form one large network. The network currently supports approximately 3,000 users, who may access a variety of minicomputers and mainframe computers. computers in field locations also are tied into the network or will be in the future.

At present NCTR and FDA field locations in San Francisco, Los Angeles, Denver, Seattle, Atlanta, and Orlando have access to the network through the departmental information management exchange system (DIMES), the DHHS wide-area network operated by PCC. Plans call for extending this access to all major FDA field locations. Communication with other DHHS agencies also is being developed through DIMES. CDRH's location on Piccard Drive, Rockville, Maryland, was recently connected to the network. This location has the most up-to-date wiring scheme in FDA. CDRH plans to add several TI (very large capacity) data circuits soon to support optical imaging. CFSAN is developing plans for a networking scheme for the new MOD-1 location in Beltsville, Maryland. This location will also be tied into FDA's network when the building is occupied.

The major thrust of FDA's programs in future years will be the continued achievement of the Agency's primary mission--consumer protection. In pursuing this goal, the highest program priorities will be to improve and expedite the review processes for new human drugs and for medical devices. Emphasis will also be placed on improving the quality of the review process.

Other areas where increased emphasis will be placed are on FDA's coverage of imports and laboratory processing of samples. At the same time, NCTR will continue its research in health risk assessments as a major program area.

Major initiatives include improvements to the investigational new drug program, the AIDS program, and the improvement of childhood immunizations. To the extent to which research initiatives continue to divert human and equipment resources for the assurance of the safety and efficacy of existing vaccines, most notable the lot release programs, greater priority must be given to the automation of regulatory procedures.

A plan is being developed for the conversion and simultaneous enhancement of the present Biologics Regulatory Management Systems. Both the breadth and depth of the systems will be increased.

The submission of increasing numbers of Investigational New Drug Applications (INDs) and Product License Applications (PLAs) for biological products has made modernization of the document control system imperative. A contract was awarded for development and operation of a document control system. An integrated information processing strategy was developed which set priorities for manual and automated document control and created the necessary processes and procedures for document handling. Implementation began with reformatting of the entire collection of INDs and PLAs to improve access to data and consolidate document storage space. A computerized tracking system was developed and is operational for the INDs. Procedures are now being developed for a tracking system for PLAs.

FDA is participating in a pilot trial of an electronic Product License Application (PLA) with a firm that is collaborating in this effort by submitting both hard copy and computer disk versions of the PLA. Having the PLA available on disks will allow for a more thorough analysis of the data, provide screening for specific topics in the PLA, and make reports easier to write, in addition to reducing the cumbersome volumes of paper in the traditional PLA submission. Communication between reviewers and key firm personnel will be expedited through electronic mail.

Because of increased emphasis on FDA's coverage of imports, an import processing study has been conducted. Based on the study recommendations, a contract has been awarded to design and develop the Import Support and Information System (ISIS). This will be followed by a pilot test involving several Districts representing a cross section of the import activity. Upon completion of a successful pilot test, the system will be implemented nationwide. Since ISIS must closely interface with the Field Information System (FIS), FDA is redesigning FIS using a database management system. The implementation of ISIS will necessitate the acquisition of additional hardware and software. A Delegation of Procurement Authority has been issued by the General Services Administration (GSA) for FDA to buy new equipment over five years.

The Agency is proceeding to expand the use of the optical storage and retrieval (OSAR) system technology. It is anticipated the technology will have a significant impact on the Agency's document storage and retrieval operations. An operational document imaging system will be implemented based on the prototype system operated over the last two years. Completion will take several years.

FDA is participating in several pilot projects with the regulated industry to evaluate the use of computer technology in the review of data in new drug applications (NDAs). These efforts are likely to continue for some time. Also, an initiative to develop the capability and establish guidelines to offer electronic submission of New Animal Drug applications will also be pursued.

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